EPMedSystems

Digitally signed by Ceaicovschi Tudor
Date: 2026.07.01 10:30:42 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

EP-4™

The Computerized Electrophysiology Stimulator

System Manual

CE 0473

EP MedSystems, Inc.
575 Route 73 North - Building D
West Berlin, New Jersey 08091
U.S.A.
856-753-8533

Document # 8258 Rev. C
Part # 04-1527-0000
Software Version 1.1.0

remove cover. Refer service to qualified personel

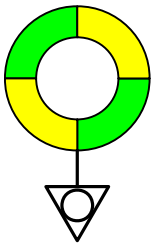
only qualified personnel to service this unit.

The EP-4 has no field serviceable internal parts. If service is required contact EPMedSystems Technical Support in the United States at 1-856-753-8533.

DANGER: Explosion Hazard, do not use in presence of flammable anesthetics

This cautionary note informs the user that this device may promote ignition of a flammable gas if operated in presence of flammable anesthetics.

The user should not operate this device in such condition under any circumstances.



Equipotential Post:

This device is specified to operate only with a medical grade grounded power cord.

Should the user elect to utilize additional grounding to the device, this post provides a central equipotential connection post.

Front panel

The stimulus outputs, power switch and the associated indicators are conveniently located on the front panel of the stimulation module shown in Figure 1-1.

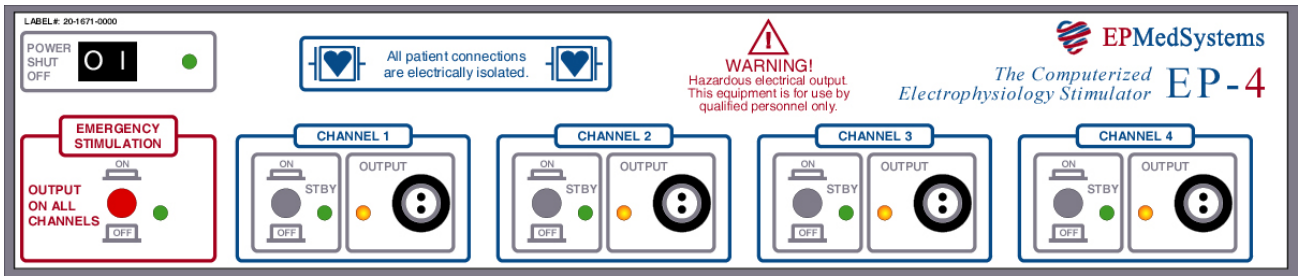


Figure 1-1 – EP-4 Front Panel (4 channel version)

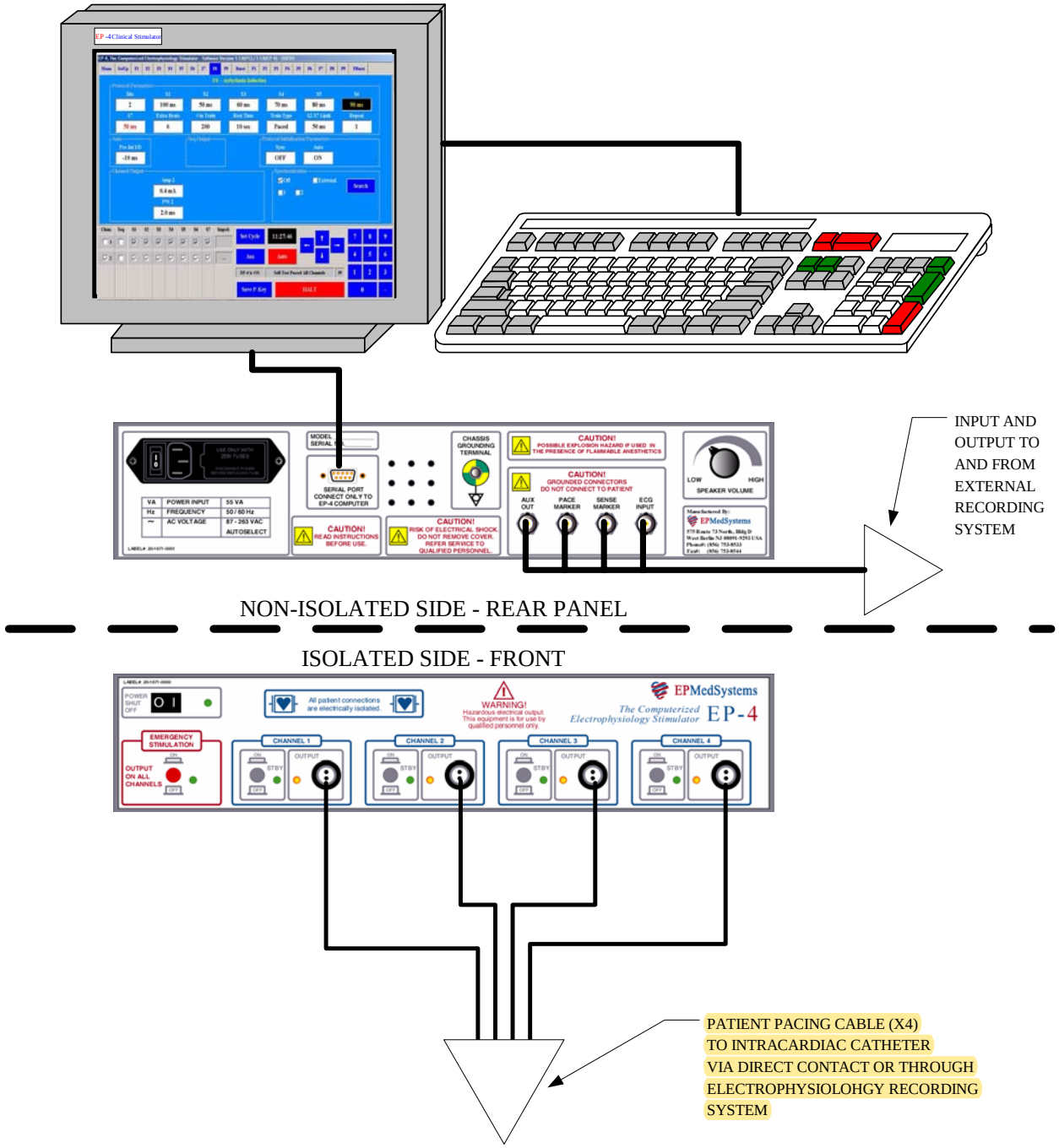


Figure 2-1 EP-4 Connection Diagram

Computer communication cable

- Attach the communication cable to the socket labeled “Serial Port 10101” on the rear of the stimulation unit and to the “COM1” connector on the rear of the computer base. Tighten the thumb or jack screws on the both sides of the serial cable.

Stimulus Protocols

The first selection listed on the main menu is F1, the "Threshold Determination" protocol. This protocol is designed to conveniently determine the current threshold at the selected site. The protocol is executed by pressing the **F1** key.

- **Select the Threshold Determination protocol by pressing the** F1 **key.**

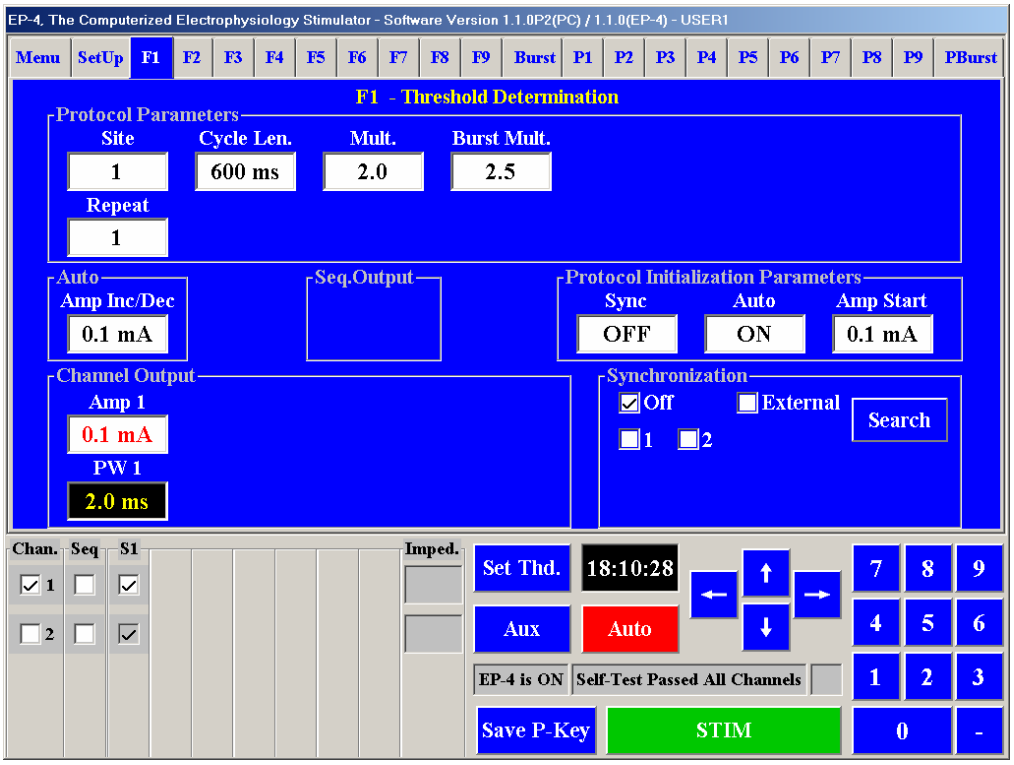


Figure 3-1 Threshold Determination Screen

Pressing a protocol key stops all stimulation and displays the selected protocol. Examine for a moment the Threshold Determination screen.

All the screens of the stimulus protocols have a similar layout. The title, together with the key used to invoke the protocol, is displayed on the top line of the protocol tab.

The central part of the display contains rows of boxes. These boxes are the parameters for the protocol. The parameter

(Figure 4-1). At this time, the stimulator is awaiting selection of one of the protocol keys.

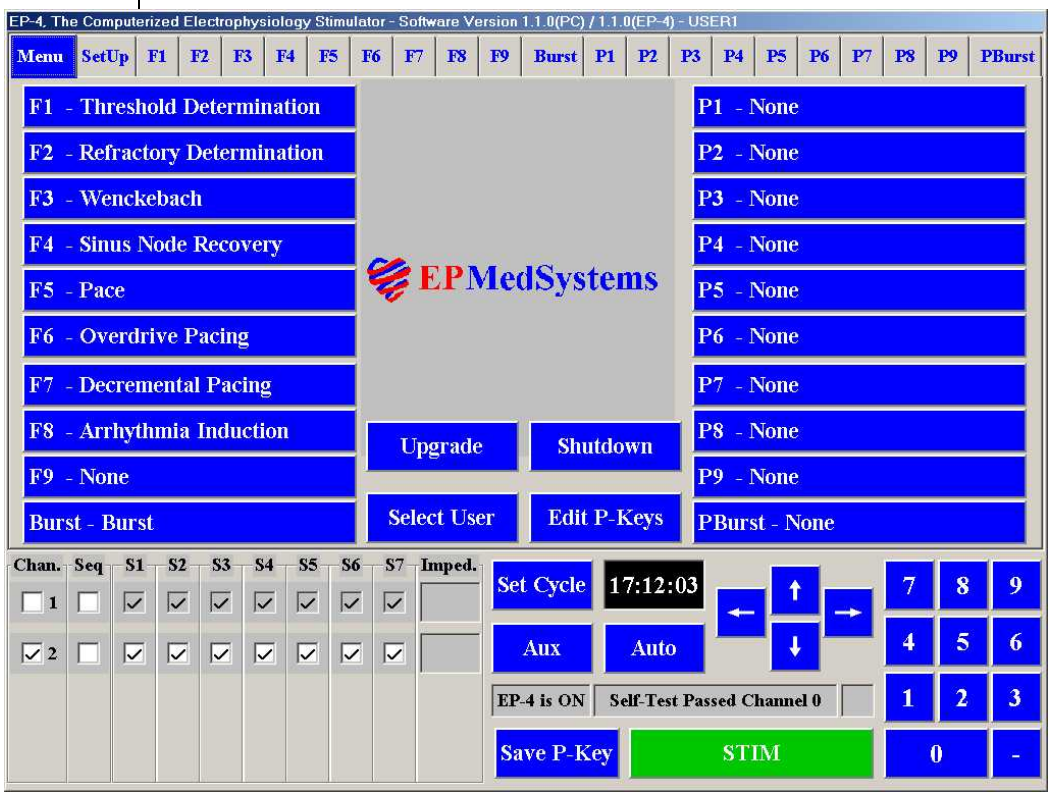


Figure 4-1 Main Menu Display

Menu Key

The user can return to this display at any time by pressing the MENU key. If a stimulus protocol is executing at the time the MENU key is pressed, stimulation is halted and the menu appears. The left side of the menu lists the pre-programmed protocols by the key used to access them, F1-F9 and their names. The right side of the menu displays the contents of the nine custom protocol keys P1-P9.

Stimulus protocols are selected from the menu by pressing the key or button (F1–F9, P1–P9, PGMD-BURST, BURST) corresponding to the protocol desired.

Shutdown Button

The **Shutdown** button will halt the application and prompt you to turn off the touch screen PC computer.

If the EP-4 is still turned on, it will prompt you to turn it off first before continuing to shut down the computer.

Protocol Screen Format

A protocol screen is divided into areas containing parameter fields, controls and information.

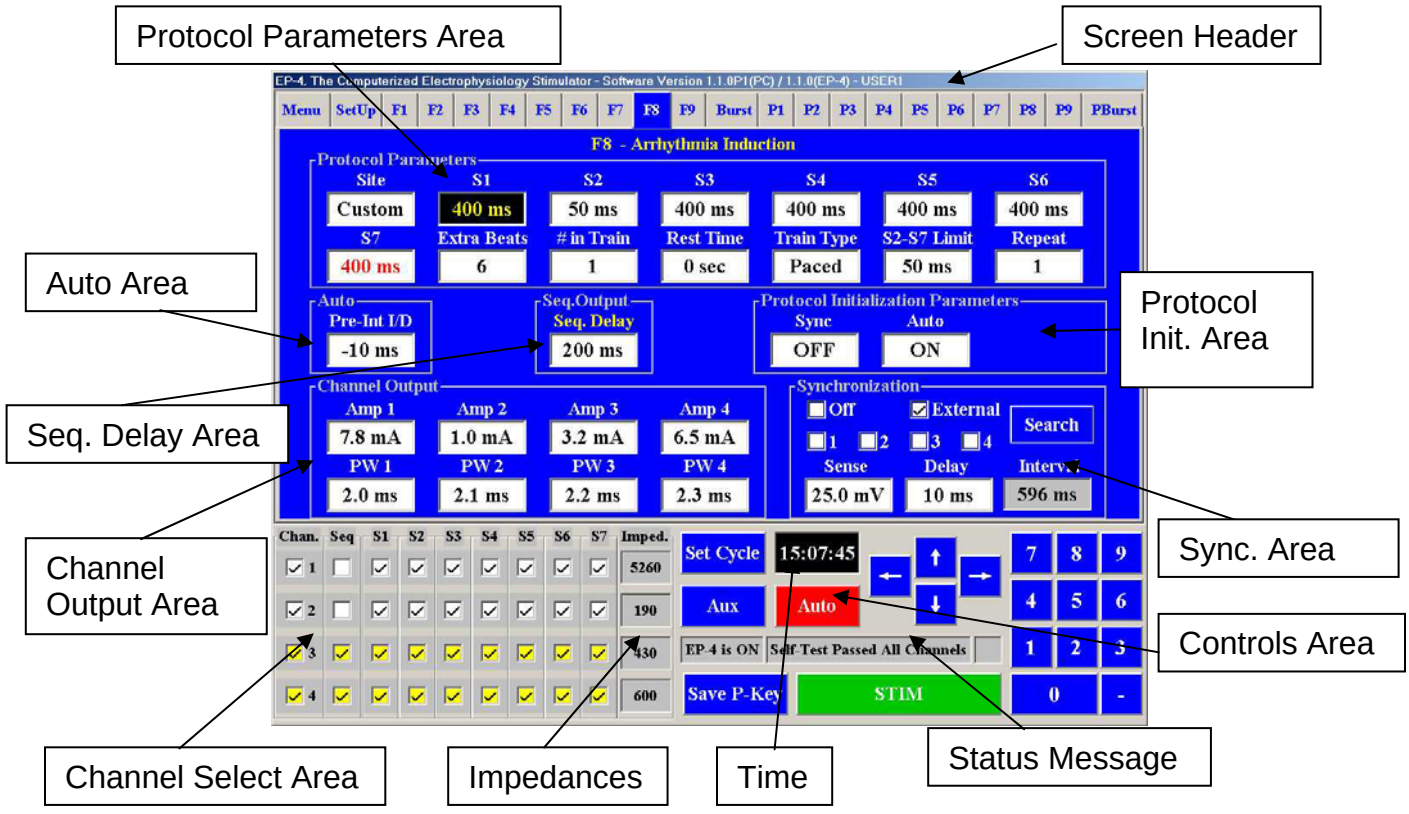


Figure 4-2 EP-4 Display Screen

Screen Header

A screen header will always be present (after the system initialization screen) during EP-4 operation. The header will contain the software version and the user name.

APPENDIX

A

Specifications

Isolated Stimulus Channels: 4

Stimulus Channel On Off Button:
4 Standard Output Channel Buttons
1 Emergency Pacing Button. Output out of channel 1-4 simultaneously

Pulse Amplitude (constant current source)**:**

Range:	0.1 – 20	mA	(2500 Ω load)
Increment:	0.1	mA	
Accuracy:	5% or 0.1	mA	(whichever is larger)

Impedance Measuring:

Range:	10 to 10,000 Ohm Load
Accuracy:	±5% above 1mA, ±10% above 5,000 Ohm

Pulse Duration

Range:	0.1 – 10.0	msec	
Increment:	0.1	msec.	
Accuracy:	0.05	msec.	(Pulse amplitude > 1 mA)

Interstimulus Interval (ISI)

Range:	S1	100–30000	msec
	S2-S7	50-10000	msec
	Burst	10–1000	msec
Accuracy:	±1 msec		
Increment:	1 msec		

Sequential (AV) Delay:

Range:	10-1000 msec
Accuracy:	±1 msec
Increment:	1 msec

Preprogrammed Protocols: 9

Threshold Determination, Sinus Node Recovery
Overdrive Pacing, Decremental Pacing, Refractory study
Arrhythmia Induction, Burst, Pace
Wenckebach block

Programmable Protocol Keys: 10

Number of Extrastimuli: 6 (S2-S7)

Emergency Pacing Function
1000 msec cycle length
10 mA constant current
2 ms pulse duration
Output out of Channel 1-4 simultaneously

External Non-Isolated Sensing (ECG Trigger from ECG Input):

Input range:	1mV - 0.5V	In 0.1mV steps to 10mV 1.0mV steps to 0.5V
Absolute max. input:	±5V	
Minimum refractory:	50 msec	After the start of the pacing pulse
Frequency range:	3.5-250Hz	

Internal Isolated Sensing (ECG Trigger from Stimulation Channels:

Input range:	0.1mV - 10mV in 0.1mV steps
Absolute max. input:	±500 mV
Minimum refractory:	50 msec after the start of the pacing pulse
Frequency range:	30-250Hz

Additional Outputs:

Four marker outputs:
- Pace Marker.
- Aux Out - Auxiliary/Paper advance.
- Sense Marker.

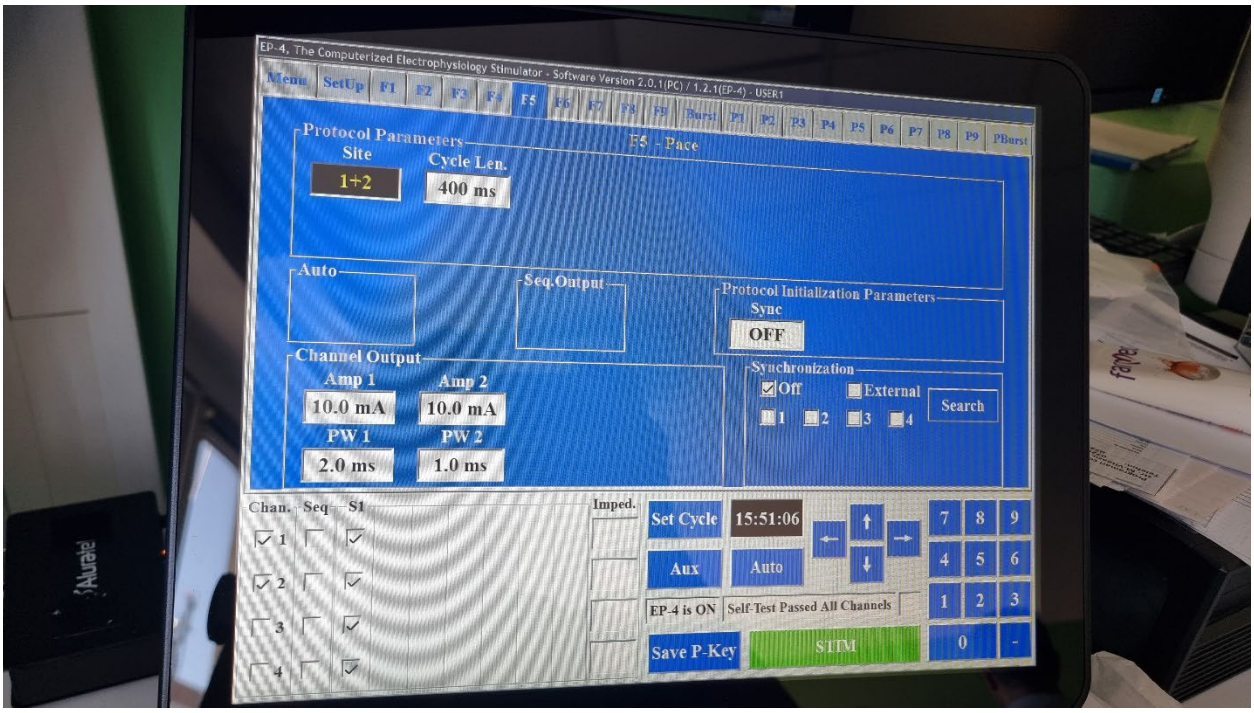
Pulse Type:
- Output voltage 0 to 5V

Audible Output:

Variable Volume control between 0dB-30dB output

Power Source:

Line Power, 83-267 VAC
Line Frequency: 50/60 Hz
Rated Power: 55W (87-263 VAC, 50-60 Hz)


EP-4, The Computerized Electrophysiology Stimulator - Software Version 2.0.1(PC) / 1.2.1(EP-4) - USER1
Menu
SetUp
F1
F2
F3
F4
F5
F6
F7
F8
F9
Burst
P1
P2
P3
P4
P5
P6
P7
P8
P9
PBurst
Protocol Parameters
Site
1+2
Cycle Len.
400 ms
F5 - Pace
Auto
Seq.Output
Protocol Initialization Parameters
Sync
OFF
Channel Output
Amp 1
10.0 mA
Amp 2
10.0 mA
PW 1
2.0 ms
PW 2
1.0 ms
Synchronization
Off
External
1
2
3
4
Search
Chan.
Seq
S1
Imped.
Set Cycle
15:51:06
Aux
Auto
EP-4 is ON
Self-Test Passed All Channels
Save P-Key
STIM
7
8
9
4
5
6
1
2
3
0
-

Specifications

RF Output Power	1 to 100 W adjustable in steps of 1 W
Impedance Range	Measures 50 Ω to 300 Ω in steps of 1 Ω
Target Temperature	15° C to 80° C adjustable in steps of 1° C
RF Delivery Time	1 to 999 seconds adjustable in steps of 1 second
Control Modes	Temperature; power
Energy Delivery modes	Independent; sequential; simultaneous
Operating Parameters	Values are digitally displayed on the Ampere™ Generator front panel
Generator Dimensions	266.7mm H x 360.68mm W x 363.22mm D (10.5” H x 14.2” W x14.3” D)
Generator Weight	9.98 kg (22.0 lbs)
Supply Voltage	100-240 VAC, 50/60 Hz
Safety Class	Class I; Type CF according to IEC 60601-1
Remote Control Console	User select/adjust: power; temperature; impedance; time
Remote Control Console Dimensions	121.92mm H x 355.6 W x 208.28 D (4.8” H x 14.0” W x 8.2” D)
Remote Control Console Weight	2.95 kg (6.5 lbs)

Category	Product Description	Item Number
Generator	Ampere™ Generator	H700489
	Ampere Generator and Remote Control	H700493
	Ampere Generator Kit (includes Generator, Remote Control, 2.5m Footswitch, Accessories)	H700495
	Ampere Generator Accessories	H700505
Remote Control	Ampere™ Remote Control	H700491
Footswitch	Footswitch, 2.5m	H700498
	Footswitch, 5m	H700499
	Footswitch, 10m	H700500
	Footswitch, 15m	H700501

Ampere™ RF
Ablation Generator

St. Jude Medical Inc.
Global Headquarters
One St. Jude Medical Drive
St. Paul, Minnesota 55117
USA
+1 651 756 2000
+1 651 756 3301 Fax

St. Jude Medical
International Division
One Lillehei Plaza
St. Paul, Minnesota 55117
USA
+1 651 756 2000
+1 651 756 2291 Fax

St. Jude Medical S.C., Inc.
U.S. Division
6300 Bee Cave Road
Bldg. Two, Suite 100
Austin, TX 78746
USA
+1 512 732 7400
+1 512 732 2418 Fax

SJM Coordination Center BVBA
The Corporate Village
Da Vincilaan 11-Box F1
B-1935 Zaventem, Belgium
+32 2 774 68 11
+32 2 772 83 84 Fax

St. Jude Medical Brasil Ltda.
Rua Itapeva, 538
5º ao 8º andar
01332-000 – São Paulo – SP
Brazil
+55 11 5080 5400
+55 11 5080 5423 Fax

St. Jude Medical (Hong Kong) Ltd.
Suite 1608, 16/F Exchange Tower
33 Wang Chiu Road
Kowloon Bay, Kowloon
Hong Kong SAR
+852 2996 7688
+852 2956 0622 Fax

St. Jude Medical Japan Co., Ltd.
Shiodome City Center 15F
1-5-2 Higashi Shinbashi, Minato-ku
Tokyo 105-7115
Japan
+81 3 6255 6370
+81 3 6255 6371 Fax

St. Jude Medical Australia Pty, Ltd.
17 Orion Road
Lane Cove, NSW 2066
Australia
+61 2 9936 1200
+61 2 9936 1222 Fax

SJMprofessional.com

ST. JUDE MEDICAL™

Rx Only
Brief Summary:
Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

ID-2000131 A EN (02/14)

ST. JUDE MEDICAL™

WHAT IF AN RF ABLATION GENERATOR WAS BUILT FROM THE GROUND UP TO SEAMLESSLY ADDRESS YOUR NEEDS?

The Ampere™ RF Ablation Generator sets new standards for electrophysiology (EP) lab integration and operation. The enhanced features allow for more user control and customization, as well as seamless connectivity to other St. Jude Medical™ EP lab equipment.

TURNING WHAT IF INTO WHY NOT™

EP Lab Integration

The Ampere™ RF Generator was specifically designed to work alongside the EnSite™ Velocity™ Cardiac Mapping System and includes an integrated *GenConnect* module for easy use. In addition, the Ampere generator is designed for the EP-WorkMate™ Recording System, including the WorkMate™ Claris™ System, and other major recording systems. The Ampere generator will also work with the entire current ablation offering from St. Jude Medical, including standard and irrigated ablation catheters and accessories, as well as the Cool Point™ Irrigation Pump. What physicians receive from this is a robust generator option that gives them the best experience with the EnSite Velocity system and other tools they need in their laboratory.

Enhanced Functionality

The versatile Ampere RF ablation generator operates in power or temperature control mode with irrigated or standard tip ablation catheters. Additionally, it features a variable power ramp-up time and user-defined automatic irrigation flow adjustment to best suit the physician and the procedure needs. Lastly, the Ampere generator can directly control your Cool Point pump to adjust flow settings.

Ease of Use

We designed the new user interface with simplified, intuitive controls and easy-to-navigate menu options so that lab staff can become proficient quickly. Users can now access four programmable user presets to allow for quick switching between settings. It is also available with an optional Remote Control Module that allows the Ampere generator to be operated wherever it is best and most convenient for the lab and procedure.

Ampere™ RF Ablation Generator

Product Highlights

- Specifically designed to work alongside the EnSite™ Velocity™ Cardiac Mapping System, including an integrated *GenConnect* module
- Designed for compatibility with EP-WorkMate™ Recording System, WorkMate Claris™ Recording System and other major recording systems
- Choice of power or temperature control modes
- Large, colorful screen and buttons for easy reading and programming
- New programming options, including automatic irrigation flow adjustment and variable power ramp-up times
- Up to four presets for easy switching between settings
- Optional full-color screen remote control and footswitch available

Ordering Information

Reorder Number	Description
H700495	Ampere™ Generator Kit (includes generator + footswitch, 2.5 m cable)
H700491	Ampere™ Remote Control (includes 15 m fiber cord)
H701337	Remote Control Fiber Cord, 10 m
H701338	Remote Control Fiber Cord, 15 m
H701339	Remote Control Fiber Cord, 30 m
H700498	Ampere™ Footswitch, 2.5 m
H700499	Ampere Footswitch, 5 m
H700500	Ampere Footswitch, 10 m
H700501	Ampere Footswitch, 15 m

Ampere™ RF Ablation Generator

Ampere™ Remote Control

ST. JUDE MEDICAL

Display, Controls, and Connections

Front Panel Controls

Figure 1. *Front Panel Controls*

Callout	Name	Description
1	RF energy delivery Button	• Press to begin delivery of RF energy. Press again to stop RF energy delivery.
2	Menu Button	• Displays/hides the Menu.
3	Menu Knob	• Rotate the knob to navigate through the menu options. • Press the knob to select a menu option.
4	Preset Button	• Displays the Preset menu (4 assignable presets and default settings).
5	Standby Button	• Red light is on while in standby (Standby message displays on-screen). • Press to toggle On/Off Standby. • Both the main and Remote unit Standby buttons must be Off to disengage Standby.
6	EGM Connector	• For connecting to an EP recording system to display the intracardiac signal.
7	Indifferent Electrode Connectors (2)	• For connecting the Ampere™ Generator to the Disposable Indifferent Patches.
8	Catheter Extension Connector	• For connecting the catheter to the Generator.
9	Arrow Buttons	• Press up (increase) or down (decrease) arrows to adjust parameter settings: • Power (Watts), Temperature (°C), Impedance (Ω), Time (Seconds)

Display Panel

Therapy data display, parameter adjustments, and generator setup are made through the display panel.

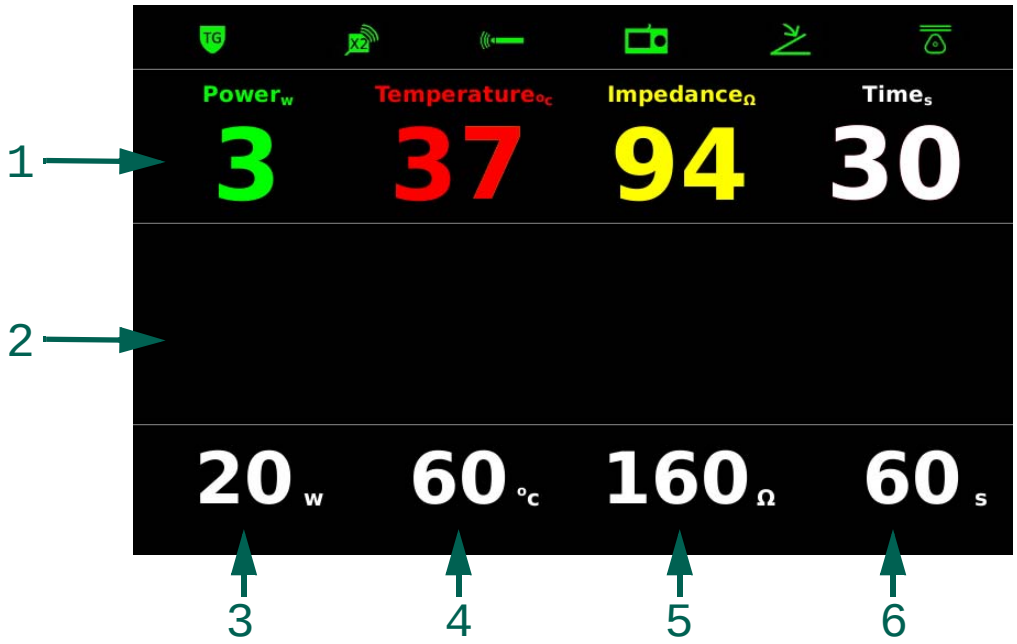


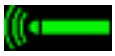
Figure 2. *Display Panel*

Callout	Name	Description
1	Real-time Display	• Displays Power, Temperature, Impedance, and Time values as therapy is being delivered. Displays Temperature and Impedance when RF energy is not being delivered.
2	Display	• Menu display area and therapy feedback.
3	User Set Power	• Watts of power to be delivered to the catheter location. • Arrows increase/decrease power threshold in 1 Watt increments.
4	User Set Temperature	• Temperature to be reached at the catheter sensor location. • Arrows increase/decrease temperature threshold in 1°C increments.
5	User Set Impedance	• Impedance between the ablation electrode and the DIP electrode(s). If impedance goes above set limit, RF energy delivery stops. • Arrows increase/decrease impedance threshold in 1Ω increments.
6	User Set Time	• Time elapsed from when the RF energy delivery button was pressed -- RF energy delivery stops when the set time is reached. • Arrows increase/decrease time duration in 1 second increments.

Connection Icons

The Connection Icons indicate the state of connected accessories:

Figure 3. *Connection Icons*

Icon	Name	State	Description
	TempGuard™ Feature	Gray	• The TempGuard™ feature is not enabled.
		White	• The TempGuard™ feature is enabled and ready.
		Green	• The TempGuard™ feature is active.
	DIP X2	Gray	• Programmed RF energy delivery power is ≤ 50 Watts — only one Disposable Indifferent Patch is required.
		Yellow	• Programmed RF energy delivery power is > 50 Watts — two Disposable Indifferent Patchs are required.
	Catheter	Gray	• Catheter is not connected.
		Green	• Catheter is connected.
	Remote Control	Gray	• Remote control is not connected.
		Green	• Remote control is connected and communicating with the Ampere™ Generator.
	Footswitch	Gray	• Footswitch is not connected.
		Green	• Footswitch is connected and communicating with the Ampere™ Generator.
	Pump	Gray	• Pump is not connected.
		White	• Pump is connected and ready.
		Green	• Pump is running.

Cool Point™ Irrigation Pump

Product Highlights

- Peristaltic pump
- Two-way communication with the IBI-1500T11 Cardiac Ablation Generator
- 2 microliter bubble detectors
- In-line pressure sensor to detect downstream occlusion
- Compact, lightweight design
- Ergonomic carrying handle
- Includes: Irrigation Pump, Power Cord, Pole Clamp, 1779 Connecting Cable, Operator's Manual

Ordering Information

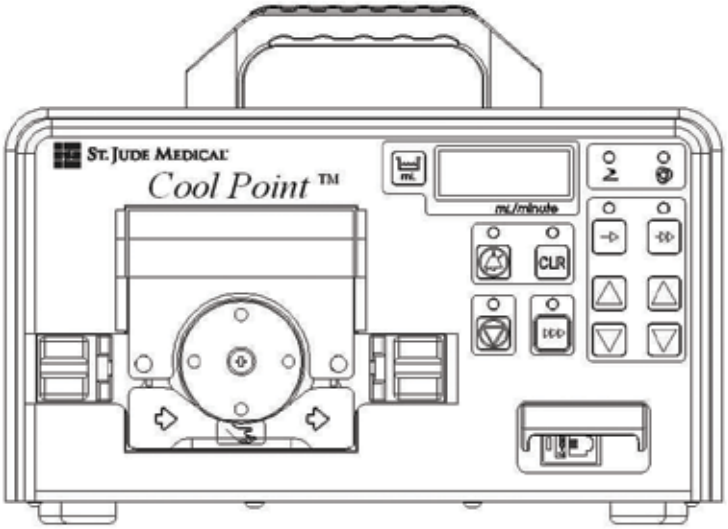
Reorder Number	Description
85784	Cool Point™ Irrigation Pump

Required Cool Point Tubing Set

Reorder Number	Description	Length (cm)
85785	Cool Point™ Tubing Set (sold individually)	329

Required Cool Point Accessories

Reorder Number	Description	Length (cm)
85786	Communications cable, 20-feet, between Cool Point™ Irrigation Pump and IBI-1500T11 Cardiac Ablation Generator	600



SJM-CAG-0915-0035(1) | Item approved for international use only.

ST. JUDE MEDICAL

Cool Point Irrigation Pump

Designed Specifically for Irrigated Ablation

Features

- Fully integrated with the St. Jude Medical Irrigated Ablation System:
  - Therapy™ Cool Path™ family of irrigated ablation catheters
  - IBI-1500 T11 cardiac ablation generator
- Convenient set-up. Easy-to-use controls
- Safety features automatically enabled

ST. JUDE MEDICAL

Cool Point Irrigation Pump

Engineered for Control, Safety, and Ease of Use

Control

- Direct communication with IBI-1500T11 cardiac ablation generator
- Fully programmable flow rates – up to 40 ml/min*
- Tracks and displays total irrigation volume

Safety

- Exclusive in-line occlusion detection
- Dual bubble detectors:
  - 2 µL air bubble detection
  - Bubble detection diagnostic self-check

Ease of Use

- Plug-and-play use with IBI-1500T11 cardiac ablation generator
- Flow rate displayed on highly visible LED
- Compact size, lightweight design – can be mounted on an IV pole

Cool Point Tubing Set specially designed for easy connection. An in-line occlusion sensor helps ensure safe operation.

Specifications

Mechanism:	Peristaltic
Dimensions:	29 cm x 21 cm (including handle) x 18.5 cm (including pump head) (W x H x D)
Weight:	3.75 kg
Flow Rates:	Low flow: 1 to 5 ml/min (1 ml/min increments)
	High flow: 6 to 40 ml/min (1 ml/min increments)
Priming Flow Rate:	60 ml/min
Air Bubble Detection:	2 µL
Alarms:	Bubble detection; communication lost; door open; pressure sensor not connected; occlusion

Ordering Information

Item Number	Description
85784	Cool Point Irrigation Pump
85786 (Model Number 1779)	Communication cable for the Cool Point Irrigation Pump
85785	Cool Point tubing set (sold individually)

*When the Cool Point irrigation pump is used with Therapy Cool Path irrigated ablation catheters, a maximum flow rate of 17 ml/min is recommended.

Visit our website: sjm.com/irrigatedsystem
For further information, please call:

Product manufactured by Irvine Biomedical, Inc., a St. Jude Medical Company.

Information contained herein for distribution outside of the US only.

ST. JUDE MEDICAL

CE 0086

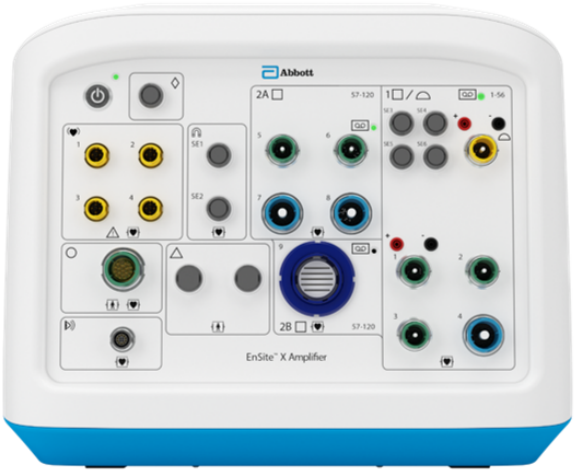
St. Jude Medical, Inc.
Global Headquarters
One Lillehei Plaza
St. Paul, MN 55117
651 483 2000
Telex: 298453
651 766 3045 Fax

St. Jude Medical Europe, Inc.
The Corporate Village
Avenue Da Vinci laan, 11 - Box F1
B-1935 - Zaventem
Belgium
+32 2 774 68 11
+32 2 772 83 84 Fax

St. Jude Medical Brazil Ltda.
Rua Frei Caneca, 1380-9 A-CJ91/92
Sao Paulo - SP - Brasil
CEP 01307-002
+55 11 5080 5400
+55 11 5080 5423 Fax

St. Jude Medical (Hong Kong) Ltd.
Unit 2701-07, COSCO Tower,
Grand Millennium Plaza
183 Queen's Road,
Central, Hong Kong
+852 2996 7688
+852 2956 0622 Fax

= Direct cables



ENSITE X AMPLIFIER PORT	PIN NUMBERS
1	1-10
2	11-20
3	21-30
4	31-52
ABLATION	53-56
5	57-66
6	67-76
7	77-98
8	99-120
9	57-120

Figure 15. New Study/New Patient Screen

1. Select New Patient button. (selected by default)
2. Enter patient information into the fields, required information is noted.

   NOTE: Patient ID and weight cannot be changed after leaving this screen.
3. Select the Navigation Mode.

   NOTE: Navigation mode cannot be changed after leaving this screen.
4. Select the Lab.

   NOTE: Lab cannot be changed after leaving this screen.
5. Select Begin Study button once all patient and system information has been entered. The EnSite™ X Setup Screen will appear.
6. Select the Exit button to leave the Study without saving.

   NOTE: Use the mouse to hover the pointer over the to show informational text about a selection for entry field.

Navigation Mode Description

The EnSite™ X EP System provides users with two distinct navigation modes; EnSite NavX™ mode and EnSite™ VoXel mode. Selection of a navigation mode is required before beginning a study and cannot be changed after leaving the setup screen.

The EnSite™ VoXel model should be selected when only Sensor Enabled™ catheters will be used for location data collection. In this mode, catheter locations are mainly based on the magnetic signals generated by Sensor Enabled™ catheters in conjunction with the Field Frame. Standard catheters (that is, without a sensor) can only be visualized in this mode and only after enough magnetic information has been collected near the catheter location.

The EnSite NavX™ mode should be selected when the use of standard electrophysiological (EP) (that is, without a sensor) catheters to collect location data is desired. In this mode, catheter locations are calculated based on impedance signals generated using the EnSite™ Surface Electrodes attached to the patient. Optionally, a Sensor Enabled™ catheter(s) in conjunction with the EnSite™ X Field Frame can be used in this mode to collect magnetic information. The system will use the collected magnetic information for EnGuide Stability Monitor, and during the optional EnSite NavX™ SE field scaling calculation.

Lab Description

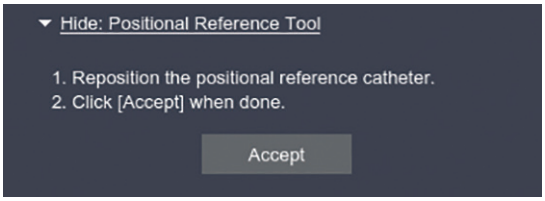
During installation, service personnel will perform a Lab characterization procedure in each room the system is planned to be used. This procedure will measure the magnetic field of the room. Selection of a lab is required before beginning a study and cannot be changed after leaving the setup screen. A "Non-Characterized Lab" is an option, but not the default. Selecting a non-characterized lab may limit C-Arm movement and may cause false detections of metal distortion.

The Lab characterization information for the selected lab will be used to correct magnetic positions due to metal distortion and prevent inaccurate data collection. If the metal environment in the lab changes (e.g. new fluoroscopy system) the lab must be re-characterized as the original data may no longer be accurate.

2. Distance Threshold slider – Controls the distance at which the EnGuide Stability Monitor triggers an alert to the user.
3. Electrode drop-down menu – Select the System Reference (default) or intracardiac electrode for the Positional Reference Tool.
4. Catheter in desired location checkbox – Enable to confirm that the catheter chosen for the Positional Reference Tool is in the desired location.
5. Enable Positional Reference Tool checkbox – Enable to turn on Positional Reference Tool monitoring.

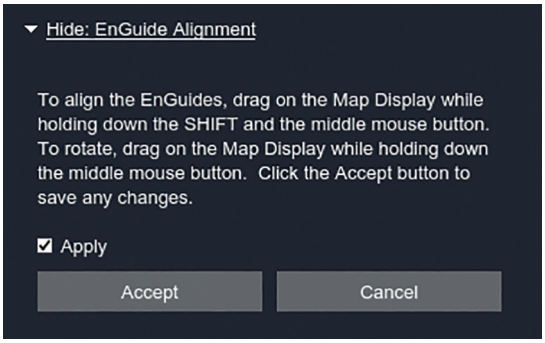
Figure 45. EnSite NavX™ Navigation Methods

EnSite NavX™ Mode, Positional Reference Tool



1. Show: Positional Reference Tool drop-down menu – Instructions and options to correct a Positional Reference Tool Catheter Dislodgement warning.
2. Accept button – Select Accept when the positional reference catheter is in the desired location.

EnSite NavX™ Mode, EnGuide Alignment



1. Show: EnGuide Alignment drop-down menu – Instructions and options to use the EnGuide Alignment feature.
2. Apply checkbox – Enable to apply the desired EnGuide Alignment.
3. Accept button – Select to Accept user changes to EnGuide Alignment.
4. Cancel button – Select to Cancel user changes to EnGuide Alignment.

EnGuide Stability Monitor (EnSite NavX™ Mode Only)

The EnSite™ X EP System can check for unexpected changes in Sensor Enabled™ EnGuide locations. If the system provides a message that instability has been detected, check for rate or rhythm changes, respiratory changes, or patient movement. If required, use EnGuide Alignment to adjust the alignment of EnGuides relative to the model. Also, check the status of the Metal Distortion Meter. If the distortion threshold is exceeded, there could potentially be a shift in the magnetic sensor positions caused by the presence of metal in the EnSite™ X EP System magnetic Field.

NOTE: The EnGuide Stability Monitor only works when actively tracking Sensor Enabled™ EnGuide locations. A Sensor Enabled™ catheter is required to be in the body, with EnSite™ NavX SE Field Scaling applied.

Show Positional Reference Tool (EnSite NavX™ Mode Only)

The Positional Reference Tool is a software feature available when operating in EnSite NavX™ mode procedures with an intracardiac positional reference selected. This feature alerts the user when there has been acute movement of the positional reference catheter. It is designed to detect sudden movement of the positional reference catheter along its long axis that exceeds a preset distance threshold of 4mm.

This feature requires that the positional reference catheter be in a stable location throughout the procedure. It is recommended that the coronary sinus (CS) catheter be used for this purpose. The Positional Reference Tool is intended to be used with a multi- electrode positional reference catheter and requires that the positional reference catheter consist of at least 4 electrodes. The Positional Reference Tool detects positional reference catheter movement by comparing the current position of the positional reference electrode to its past position. The Positional Reference Tool examines all the electrodes on the positional reference catheter to confirm that the detected movement is due to actual physical catheter dislodgement.

By default, this feature is not enabled; however, the user can enable or disable this feature at any time during the procedure. If positional reference catheter movement is detected, the user is provided with several methods to manage the repositioning of the catheter.

NOTE: The Positional Reference Tool can only be enabled if the positional reference catheter has at least 4 electrodes. If fewer than 4 visible electrodes are defined, the Positional Reference Tool will not activate, even if the user attempts to set up and enable the feature.

Setting Up the Positional Reference Tool (EnSite NavX™ Mode Only)

NOTE: The Positional Reference Tool requires that the positional reference catheter be in a stable location. It is recommended that the coronary sinus (CS) catheter be used for this purpose.

The Positional Reference Tool requires a minimum of 4 visible electrodes on the positional reference catheter. The visibility of bad electrodes on the positional reference catheter should be turned off.

Follow these steps to set up the Positional Reference Tool:

1. Select the positional reference catheter and positional reference electrode from the Positional Reference drop-down menu.
2. When the catheter is in the desired position select the Catheter Desired Location checkbox.
3. Select the Enable Positional Reference Tool checkbox.

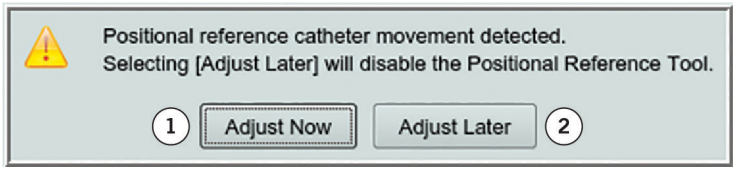
The system will display a progress bar while the Positional Reference Tool is being enabled. The catheter must be kept in a stable position and not disturbed for the duration of the Positional Reference Tool's initialization.

NOTE: Initializing the Positional Reference Tool takes approximately 10 seconds from the time that the Enable Positional Reference Tool checkbox is selected

Positional Reference Catheter Dislodgement (EnSite NavX™ Mode Only)

When the Positional Reference Tool detects that the positional reference catheter has moved at least 4mm from its previous location, a message will be displayed. The Positional Reference Tool message gives users the option to take immediate action (select Adjust Now) or to act later (select Adjust Later).

Figure 46. Positional Reference Catheter Movement Error Message



1. Adjust Now button – select to take immediate action
2. Adjust Later button – select to defer action to a later time

CAUTION:

- **Model points, mapping points, and map tags (labels, lesions, shadows, etc.) placed at EnGuide within approximately 15 seconds prior to notification of dislodgement may not be based on the previous location of the positional reference catheter. The user should confirm whether these points are valid.**
- **If the Adjust Later button is selected, the user must be aware that any tasks that rely on the positional reference catheter's location may be affected. These tasks include collecting model points, collecting mapping points, placing labels, placing lesions, etc.**
- **The Positional Reference Tool will not monitor positional reference catheter dislodgements if Adjust Later is selected.**
- **If the system notifies the user of both a surface electrode error and a Positional Reference Tool dislodgement message, the surface electrode error should be addressed first.**
- **If the system notifies the user of both a surface electrode error and a Positional Reference Tool dislodgement message, the user should verify that the positional reference catheter has physically moved after addressing the surface electrode error.**
- **Sudden impedance changes of the body or catheter electrodes caused by the connection of other devices (for example, stimulator, defibrillator, and other devices) may trigger the Positional Reference Tool. The user should verify the movement before accepting the adjustment.**

Managing Positional Reference Catheter Dislodgement

Managing the dislodgement of the positional reference catheter is done in the Navigation Setup Sub-tab or the Navigations Settings Panel.

- If Adjust Now was selected at the time of dislodgement notification, the system will immediately enter the Navigation Setup Sub-tab.
- If Adjust Later was selected at the time of dislodgement notification, the user will need to manually enter the Navigation Setup Sub-tab or the Navigations Settings Panel.

When the Navigation Setup is entered (either by selecting Adjust Now or manually selecting the Navigation sub-tab ask in the Setup workflow) the display will show the current location of the positional reference catheter as well as a preview of where the other catheters will be located if the adjustment is accepted. A yellow sphere will surround the previous location of the selected electrode on the positional reference catheter and a dashed line will connect the current location of the selected electrode with the previous location of that same electrode.

The user should assess the validity of the positional reference catheter dislodgement prior to selecting the Accept button in the Positional Reference Tool screen. The steps below discuss how to assess the validity of the dislodgement prior to accepting the new positional reference electrode location. With the Positional Reference Tool screen open:

- Assess the position of all the catheters within the field relative to the created geometry and other known landmarks.

Validate Against Fluoroscopy (if needed)

If the user does not think the catheters are shown in the appropriate locations, the user can disable and then re- enable the Positional Reference Tool by using the check box. This will disregard the notification and will not update the position of the catheters.

If the user does think the catheter are shown in the appropriate locations, the user has two options based on the perceived future stability of the positional reference catheter:

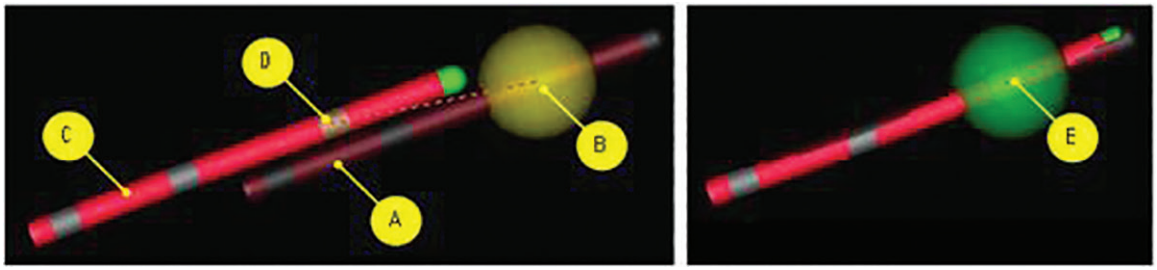
1. Manually reposition the catheter until the positional reference electrode is back to the original electrode location.

OR

2. Accept the new positional reference catheter location without manually repositioning the positional reference catheter.

If the user chooses option manually reposition the positional reference catheter, the user can use the yellow sphere and dashed line as a guide (catheter movement will appear damped). To return the positional reference electrode to its previous position, move the positional reference catheter until the positional reference electrode moves into the yellow sphere and the sphere turns green. The yellow sphere will turn green once the selected electrode is within 4mm of the previous location. When satisfied with the readjusted position, select Accept. This will reset the Positional Reference Tool with the new coordinates of the selected electrode. When the user selects Accept the new location of the positional reference catheter is set. All other catheters will be displayed relative to this new position.

Figure 47. Adjusting Positional Reference



1. A and B show the previous position of the positional reference catheter and electrode.
2. C and D show the current position of the positional reference catheter and electrode.
3. To return the positional reference electrode to its previous position, move catheter C until electrode D is within the yellow sphere, in which case the yellow sphere will turn green.
4. E shows the positional reference electrode properly adjusted.

If the user chooses to accept the new positional reference catheter location without manually repositioning the positional reference catheter the user selects Accept and the system will reset the Positional Reference Tool with the new coordinates of the selected electrode. When the user selects Accept the new location of the positional reference catheter is set. All other catheters will be displayed relative to this new position. The user should ensure that the positional reference catheter is in a clinically appropriate, stable location before selecting Accept.

A progress bar (beneath the control panel) can be seen while the re- initialization is in progress. When complete, the system will be ready for continued operation. During that time, some catheters may temporarily appear to have shifted.

Re-initializing the Positional Reference Tool takes approximately 10 seconds from the time that the Accept button is selected.

NOTE: Whenever the user selects Accept, the positional reference must be kept in a stable position and not be disturbed for the duration of the Positional Reference Tool's re-initialization.

Show EnGuide Alignment (EnSite NavX™ Mode Only)

In the Navigation Setup Sub-tab, select Show EnGuide Alignment to initiate EnGuide Alignment. If there are changes in catheter location that cannot be adapted by navigating the positional reference electrode, EnGuide Alignment allows for visually realigning the catheter to the model along the x-y-z-axes.

EnGuide Alignment is used to visually adjust the alignment of EnGuides relative to the model. To align the EnGuides in the workspace, hold down the <Shift> key and the middle mouse button, and drag the mouse. While dragging the mouse, the EnGuides will move, but the model remains stationary. Use the middle mouse button to rotate the model. Use the Apply checkbox to switch between the aligned (checkbox on) and unaligned (checkbox off) states. When satisfied with the alignment, select Accept.

Sheath Filter

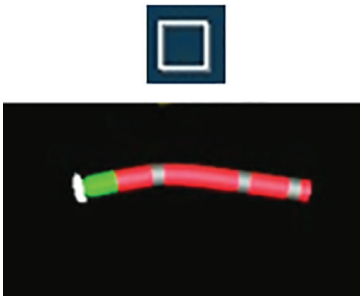
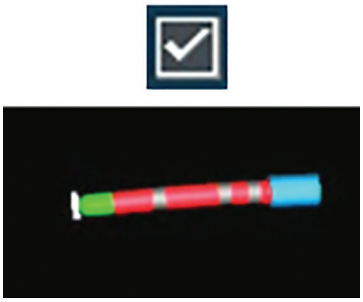
The Sheath Filter detects and provides visual feedback when all or part of a catheter is in the sheath. When an electrode is detected to be within the sheath, both visibility and data collection from the electrode will suspend.

A sheath graphic is drawn around the proximal catheter shaft to indicate that the sheath filter is active. The EnSite™ X EP System contains initial baseline setting for the Sheath Filter. The user may re-baseline the Sheath Filter to optimize performance.

NOTE: The Sheath Filter is compatible with the following 8.5F sheaths:

- Braided Swartz Transseptal Introducer
- Agilis NXT Introducer
- Baylis TorFlex
- BiosenseWebster MOBICATH

Figure 48. Sheath Filter States

Disabled	Enabled
	
Inactive	Blue colored sheath graphic. Sheath Filter is active

Sheath Filter for a Sensor Enabled™ Catheter

Sheath filter is automatically enabled for Sensor Enabled™ catheters. In EnSite™ VoXel mode, sheath filter cannot be disabled for Sensor Enabled catheters.

A Sensor Enabled catheter may be baselined to optimize performance at any time in a procedure. See rebaseline steps below.

Sheath Filter for a Standard Catheter

Sheath filter for standard catheters can be enabled or disabled in both EnSite™ VoXel and EnSite NavX™ Modes and is defaulted to "Disabled". When enabled, Sheath Filter will use initial system default settings for operation.

A standard catheter maybe rebaselined to optimize performance at any time in a procedure. See rebaseline steps below.

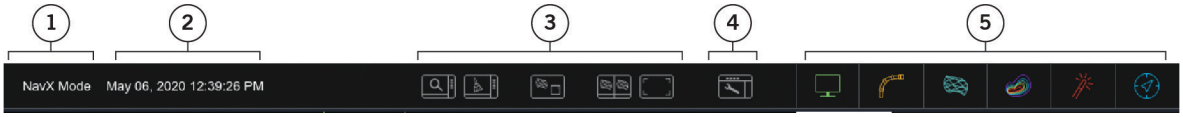
Enable/Disable Sheath Filter (not Available for Sensor Enabled™ Catheters in EnSite™ VoXel Mode)

1. Enabling/disabling the sheath filter for a standard catheter in the catheter list (checkbox).

OR

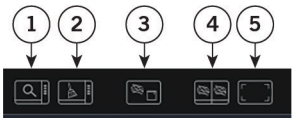
1. Right select the study workspace display.
2. Select "Sheath Filter".
3. Select catheter.
4. Then select Disable/Enable.

Figure 52. Top bar



1. Study mode Type — Displays the current mode Type (EnSite NavX™ or EnSite™ VoXel).
2. Date/Time Stamp — Displays the current Date and Time.
3. Display Options — Provides the user with the ability to change the model/map display.
4. Access to Setup Link — Provides access to setup screens (Patient/Study Details, Hardware Map, etc.)
5. Settings Panel Access Icons — Provides access to the configuration settings/options for each panel.
   - Meter & Display Options
   - Catheter & Waveforms
   - Model, DIF & Fusion Options
   - Map Settings
   - AutoMark & Contact Force
   - Navigation

Figure 53. Display Options

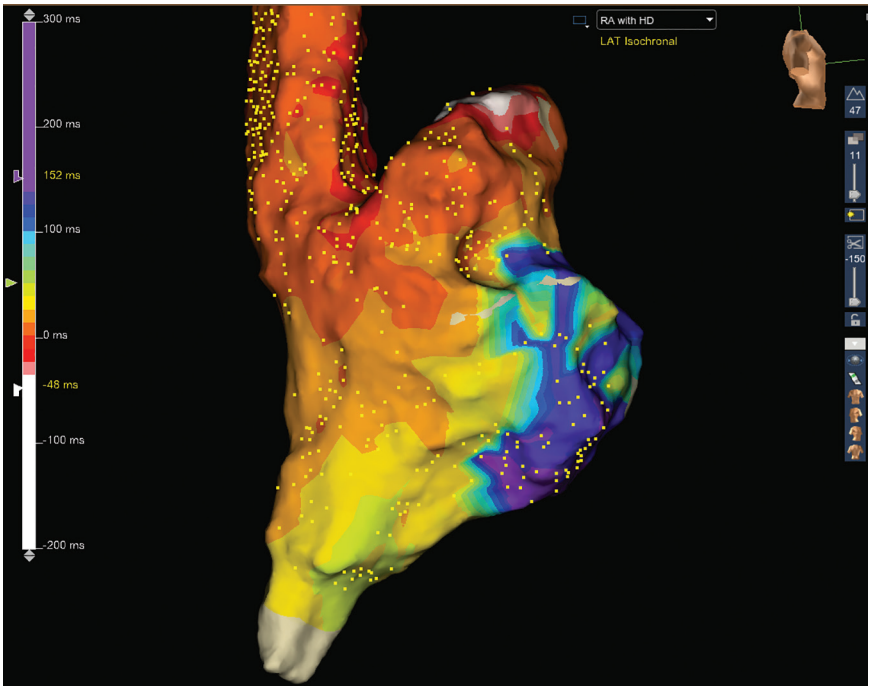


1. Auto Correct Model Visibility - Centers the model back into view, and resets display settings.
2. Clean Up Display - Temporarily hides meters, metrics, and orientation options. When in Full-screen mode also hides the Points and Tools panel.
3. Mobile Work Panel - Shows or hides the Mobile Work Panel.
4. Single View / Split View Toggle - Switches between single and split screen views.
5. Full Screen Toggle - Hides the Work Panel and displays the Model/Map area in full screen mode.

Model and Map Display Window

The area where catheters, three-dimensional models, and/or maps are displayed. The following sections will review each item displayed within the Model/Map display screen.

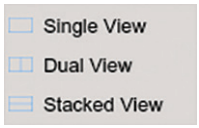
Figure 54. Map and Model Display Window



Mapping and Model Window Control: Single, Dual, and Stacked Views.

Dual View & Stacked View allow the user to display two views of the same map.

Figure 55. Mapping and Model Window Dropdown Menu



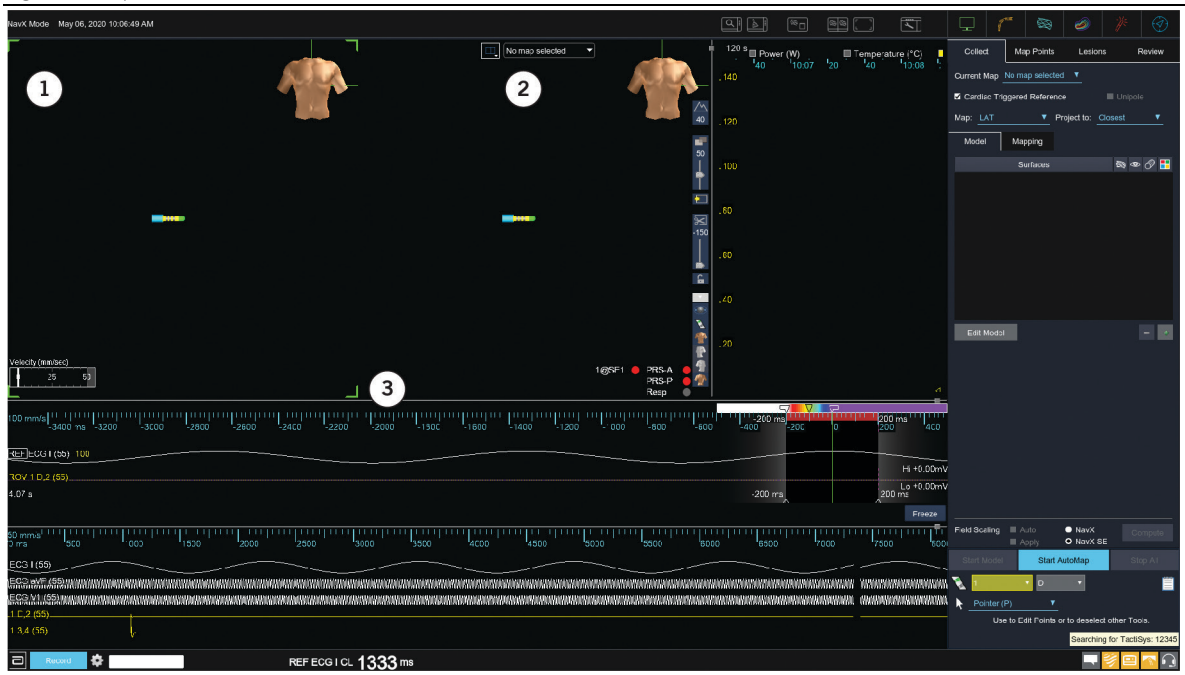
In Dual or Stacked View, the active view is highlighted by green corners, Dual View shown below. To make the other view active, click once on the black background of the non-highlighted view.

The following functions are available only for the highlighted, active view:

- Using the mouse to rotate the model.
- Adjusting the clipping plane.
- Adjusting the view scale.
- Saving or loading a model/map View.

  NOTE: Using the mouse to delete surface points or place map labels, lesion markers, anatomic markers, or tape measures can only be done in the highlighted view; however, the result of these actions appears in both model/map display areas.

Figure 56. Map and Model Dual View



1. Primary model/map display area
2. Secondary model/map display area
3. Active model/map display area

The left side of the model/map display when dual view is selected.

The right side of the model/map display when dual view is selected.

Framed with green brackets.

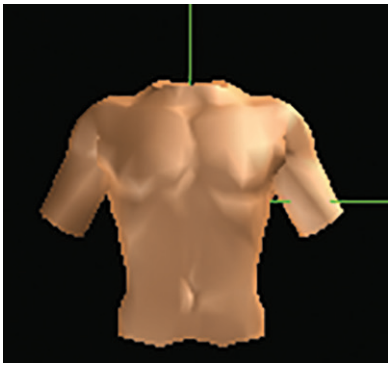
Views and the Orientation Reference

The current rotation of the display is indicated by the orientation reference icon in the upper right of the model or map display. A view is a saved orientation of a model or map (rotation and panning) that is accessible by clicking a button.

Four predefined views and up to three custom views are available. The predefined views are AP, LAO, RAO, and PA. The three custom views are user-named.

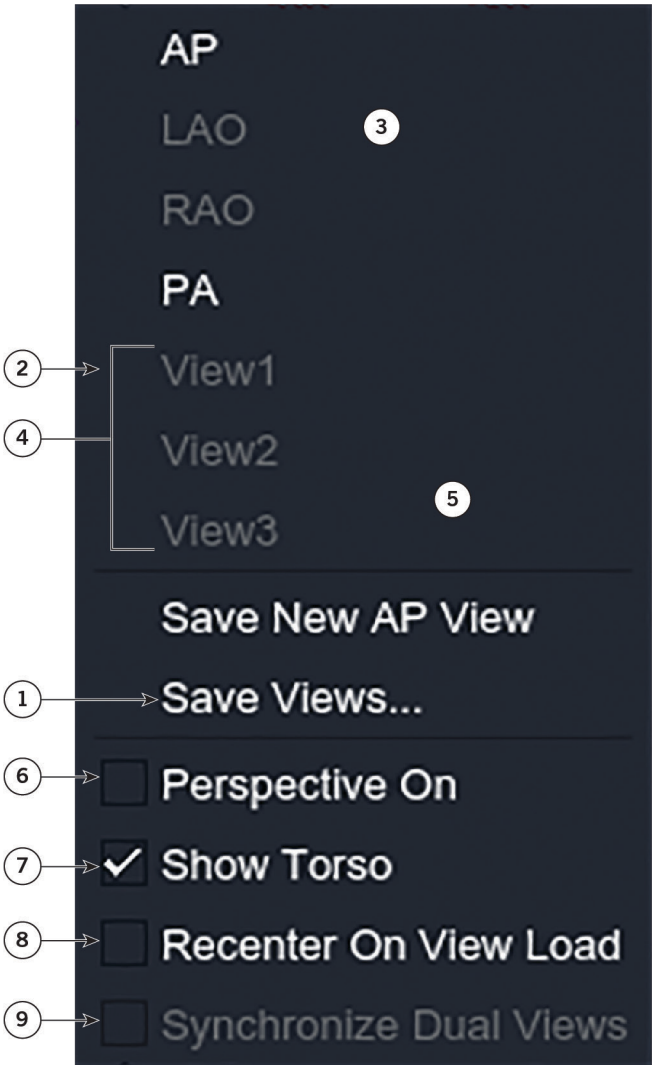
To access the view controls and the orientation reference settings, right-select the orientation reference icon.

Figure 57. Orientation Reference Icon



Right-select the orientation reference icon to open the views and orientation reference settings right-click menu

Figure 58. The Views and Orientation Reference Right-click Menu



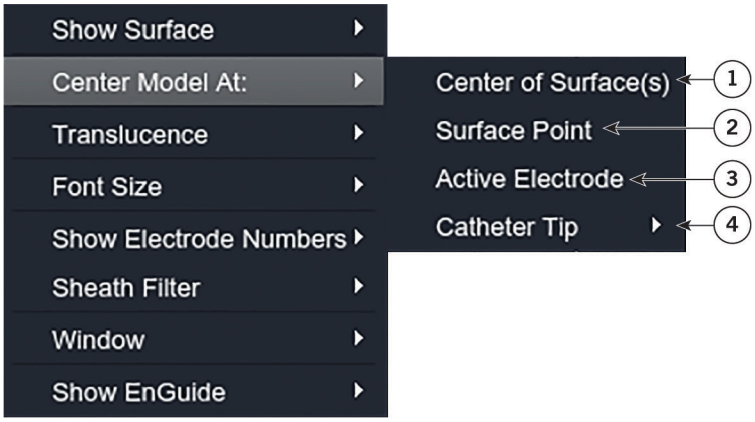
1. To save the current view and settings as a custom view, select Save Views from the right-click menu.
2. In the Save View screen, select View1, View2, or View3, and then rename the view if desired.
3. The custom view name will be added to the right-click menu.
4. Up to three custom views can be created.
5. The custom views are independent and do not compute automatically.
6. Perspective On - Perspective View displays distant objects appearing smaller than close objects, thereby enabling improved visualization of the 3D image with a clearer representation of the catheter positions. When Perspective On is selected, zooming in on the map view transforms a view of the outside surface to that of the inside surface of a chamber. When zooming out, the view of the inside surface, likewise, changes back to a view of the outside surface of the chamber. In Dual View, Perspective On works independently for each model/map display.
7. Show Torso - Shows/hides the orientation reference icon.
8. Recenter on View Load – When switching between views; AP, PA, LAO, RAO, the image is recentered.
9. Synchronize Dual-views - When in Dual View, turn this checkbox on to synchronize the orientation of the two views and allow both models or maps to be rotated at the same time.

Creating and Saving Map Views

NOTE: If a DIF model is highlighted, map views cannot be saved unless registration has been applied using the EnSite™ X Fusion Registration Module.

Right-click Menus for Mapping/Model Window

Figure 61. Center Model At Sub-menu.

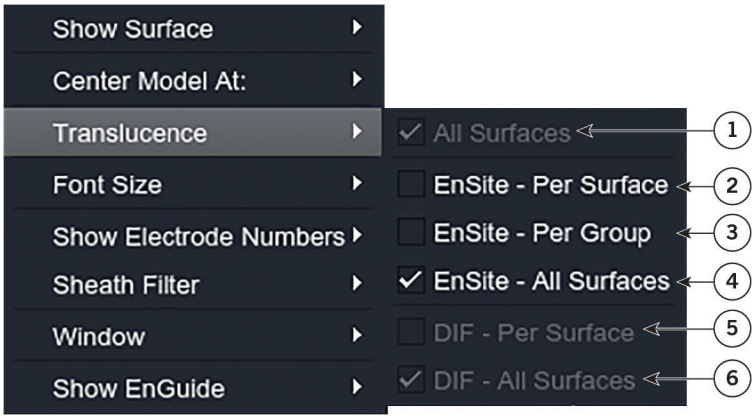


1. Center of Surface(s) – Centers the model within the view. In Dual View, it works independently for each model.
2. Surface Point – Centers the model at a selected point. When Surface Point is selected, the cursor changes to a red box with a dot in the center. With a left mouse click, select the point of interest on the model. The view is re-centered to this point, and a small marker appears at this point. Exit this mode by selecting off the model surface.
3. Active Electrode – Centers the map display to the active electrode.
4. Catheter Tip – Centers the model on the desired EnGuide.

The translucence sub-menu supports the image integration of co-located models, surface translucency can be applied independently to each surface or group. Translucency is applied to All Surfaces (both EnSite and DIF) as the default setting.

Select the Translucence menu item, then select one or more options.

Figure 62. Translucence Sub-menu.

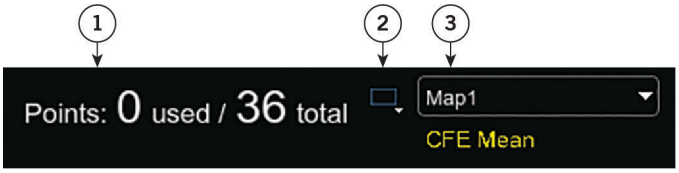


1. All Surfaces – Enable to apply translucence to all surfaces (EnSite and DIF) equally.
2. Per EnSite Surface – Enable to apply translucence to each EnSite surface independently.
3. Per EnSite Group – Enable to apply translucence to each EnSite Group (Right, Left, Other) independently.
4. All EnSite Surfaces – Enable to apply translucence to all EnSite surfaces equally.
5. Per DIF Surface – Enable to apply translucence to each DIF surface independently.
6. All DIF Surfaces – Enable to apply translucence to all DIF surfaces equally.

NOTE: When one of these modes is selected, adjustment of the translucency slider in the map display will apply to the surface, DIF, or Group currently selected within the Model or DIF list.

Map Point Count Display

Figure 63. Map Point Count Display

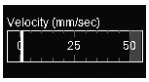


1. Displays in the Map and Model Window showing the points used and total points in the current map creation.
2. Name of the Map, drop-down menu.
3. Screen change drop-down: dual view, single view, stacked view.

Display Meters

The following meters display in the Model/Map area. Visibility controls are located in the Meters and Display Options Settings Panel. Refer to the Meters and Display Options Settings panel for more information.

Figure 64. Velocity, Respiration and Distortion Meters



Velocity (mm/s) meter – A meter that shows the relative velocity of the Active Electrode and the velocity threshold.

Respiration meter – A meter that shows the current respiration pattern.

Distortion (mm) meter – Indicates the level of possible interference of the magnetic field due to the proximity of a metal object.

Display Views

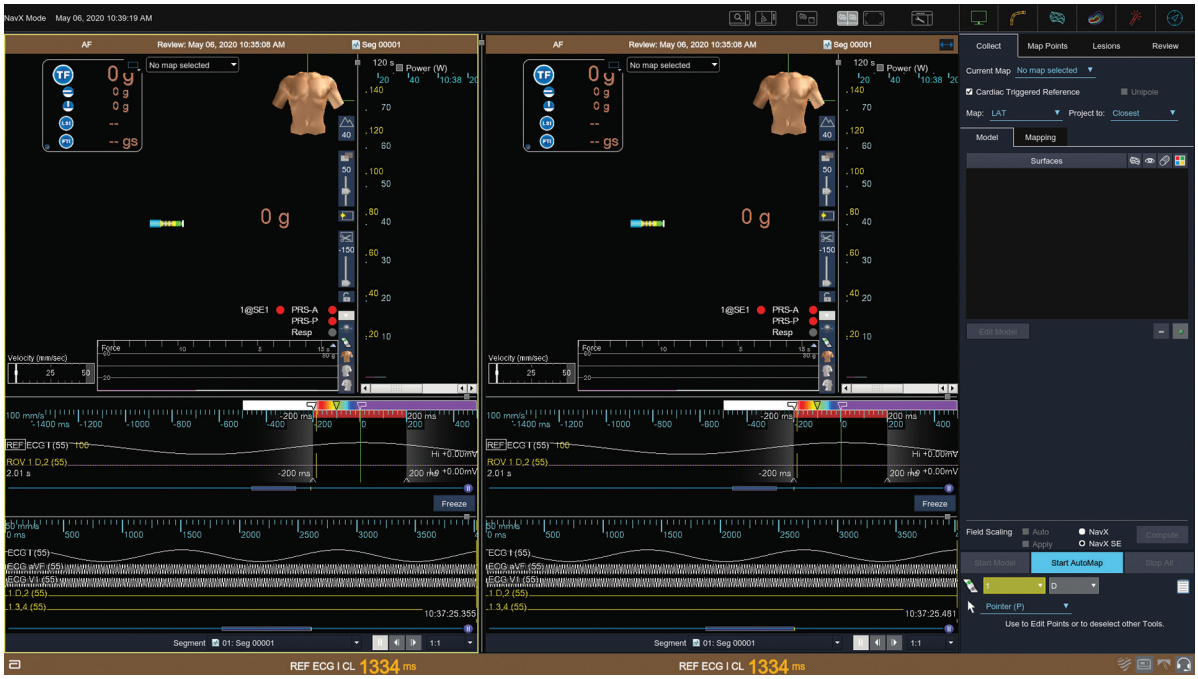
Figure 65. Split and Full Screen Views.

The Split View toggle allows the user to display combinations of Realtime and Review maps, generated with the same or different mapping points. The user can:

- Display the same map side-by-side in Realtime and Review workflows.
- Display two different maps, each generated with the same or different mapping points.
- Display one Realtime map (primary display) and one Realtime or Review map (secondary display).

NOTE: To visualize different screen arrangements, try a different screen layout preset.

Figure 66. Split Screen View



1. Primary Display: Click in this display to make it active.
2. Secondary Display: Click in this display to make it active.
3. Adjustment Bar: Click and drag to resize the display areas.
4. Yellow highlight around the active display. The Control Panel works with the active display.
5. Mapping waveform display.
6. Realtime/Review: Switch between Realtime or Review Mode.

Mobile Panel

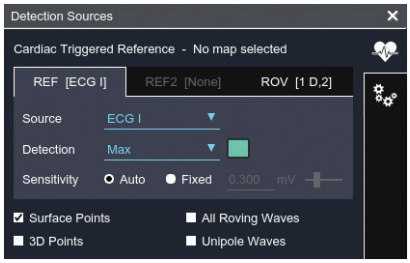
Provides access to Detection Sources and AutoMap Thresholds to support simultaneous workflow of mapping, therapy tasks, and full screen view.

To display the panel, the user selects the Mobile Work Panel button in the Display Options.

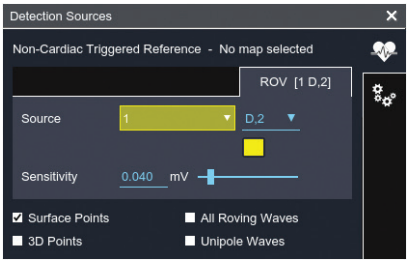
The Mobile Panel can be displayed on the screen in either Standard, Split-screen or Full Screen mode and can be positioned within the model space as desired. It is dismissed from view using the close icon in the top right corner of the panel or re-clicking the mobile work panel button within the Display Options area.

Figure 67. Mobile Panel – Detection Sources Tab

Cardiac Triggered Reference



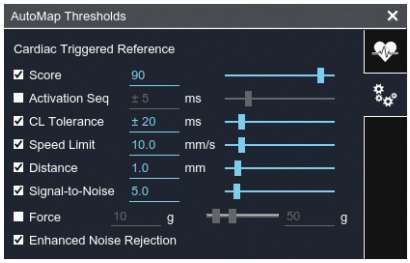
Non Cardiac Triggered Reference



Reference the Collect Tab Mapping Sub-tab for description of functionality.

Figure 68. Mobile Panel - AutoMap Thresholds Tab

Cardiac Triggered Reference



Non Cardiac Triggered Reference

Reference the Collect Tab Mapping Sub-tab for description of functionality.

Waveform Displays Window Control

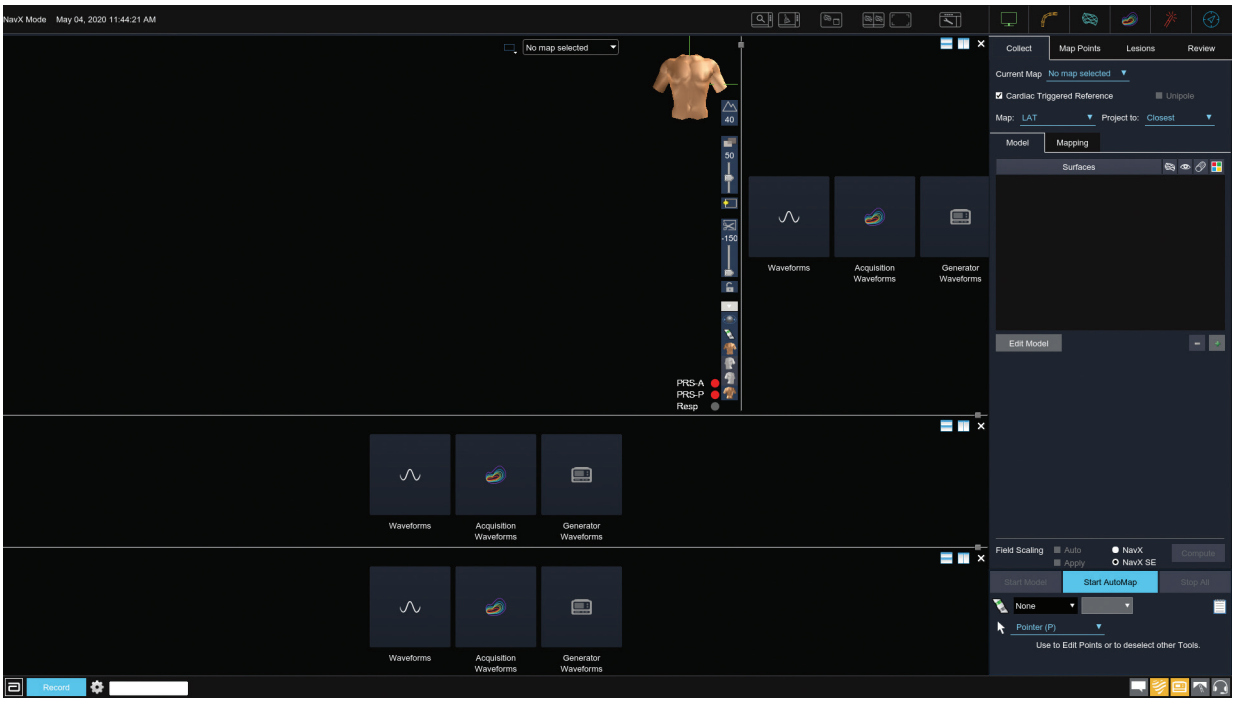
Only one waveform type can be displayed in any given screen at a time.

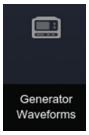
Example: If Acquisition Waveforms are displayed in the top right screen, then waveforms and generator waveforms can only be shown in the other open screens.

A different right-click sub menu opens for each of the waveform types.

> NOTE: Only one Realtime Waveforms display can be shown at a time, even when in Split Screen mode. The second Waveforms display will revert to a blank screen showing that the Waveforms content has been selected, and it will fill the screen when it can (if the display group is changed to show review data, or the Waveforms display from the other realtime display group is closed).

Figure 69. Waveform Display Controls

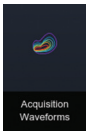


1 

Generator Waveforms: Displays Force and Ablation Generator waveforms

2 

Waveforms: Displays the active electrode signals and respiration waveforms

3 

Acquisition Waveforms: Displays the acquisition waveform

4 
The two Split Screen buttons open a second horizontal or vertical display group to the right of the original displays. The layout and content choices will be copied from original displays into the second display group.

5 
Select the "X" at the upper-right corner of the screen to close the screen.

Bottom Bar

The bottom bar contains icons that indicate the status of various system components, system information and access to controls for recording segments.

Figure 70. Bottom bar

1. Application Menu — Provides access to system level controls.
2. Segment Recording — Enables Segment Recording start/stop toggle, AutoMap and AutoMark Sessions checkboxes, and segment naming.
3. REF ECG info — Display of REF ECG info.
4. System Components — Displays the active system components.

Component Status

Figure 71. Component Status icons

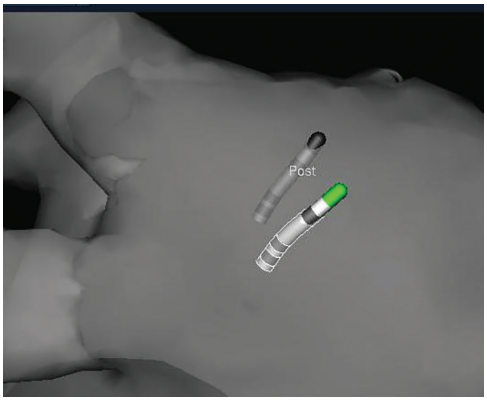
1. Messages icon – Accesses messages in the system.
2. EnSite Derexi icon – Software features that uniquely integrate the WorkMate™ Claris™ Recording System with the EnSite™ X EP System.
3. Ampere icon – Ampere Generator.
4. TactiSys Quartz icon – Shows the measurements of the contact force sensor.
5. SJM™ Connect icon – Provides access to the SJM™ Connect configuration dialogue.

EnSite™ X Application Menu


The menu bar provides access to system-level controls. All active menu bar and menu options for the current operating environment (Realtime/Offline) are displayed in white lettering. Options not available for the current operating mode are shown in gray lettering. Selecting a menu will display a column of additional options. Menu options followed by three periods "..." will display a window when selected.

Menu Option	Sub-menu Option	Function
Study and Patient Information		Displays the Study and Patient Information Screen
Save Bookmark ...		Create and save a bookmark to the notebook
Save Image …		Capture and save still images
Save Event ...		Create and save a timestamped comment to the notebook
Load DIF …		Import a three-dimensional model created from digital images sources such as CT or MRI for display in the EnSite™ X EP System
Eject External Media		Eject a CD/DVD from the DWS

Figure 77. An example of a catheter in an EnSite NavX™ study



Placing EnGuide Shadows

1. Select the EnGuide Shadows tool on the Points and Tools Panel.
2. Select a catheter from the Shadow at drop-down menu. Or select All EnGuides to place an EnGuide Shadow at the locations of all catheters.

   NOTE: EnGuide Shadow keeps the color of the displayed catheter.
3. Select Add Shadow to place an EnGuide Shadow(s) at the location of the selected catheter(s).
4. Type a name for the EnGuide shadow in the Name text area or select a name from the drop-down menu. Names appear at the middle of the EnGuide Shadow display.

   NOTE: When a shadow is placed on the map, it also appears in the EnGuide Shadow Tools List.

Anatomic Marker Tool Details

Anatomic markers connect points on the surface of the model with lines. Closed anatomic markers are useful for drawing valve or vessel openings on the model; these circular markers can be cut out of the map to show these openings. Up to 256 anatomic markers can be placed on the map.

The Marker value is displayed next to the Marker in the Model/Map Display and in the Tools List. The Marker display value is dependent upon the surfaces that it crosses.

- If a surface that the marker crosses is deleted, the marker is deleted.
- If a surface that the marker crosses is not included, the marker is hidden.

  NOTE: In EnSite NavX™ Mode, Field Scaling must be applied for values to be displayed.

The method of calculating the area differs depending on whether the marker is cut out.

- For markers that have not been cut out, the area is calculated for the entire surface encompassed by the marker.
- For markers that have been cut out, the area is calculated for an averaged plane across the open marker.

To place an anatomic marker:

1. Select the Marker tool on the Points and Tools Panel.
2. Create the marker by clicking at desired locations on the surface. The marker will be formed by connecting consecutive points.
3. Complete the marker.
4. For closed markers, click near the first point in the marker to close and complete the marker. To remove the center of the closed marker, turn on the Cutout checkbox.

   NOTE: If the marker encompasses the center of the model, the wrong portion of the model may be cut out.
5. For open markers, right-click in the display area to display the Marker menu, and then select Complete Open Marker or deselect the Marker tool or select Complete Open Marker from the Tools List.
6. Set the marker's color and thickness with the Color and Thickness controls on the Points and Tools Panel.
7. Type a name for the marker in the Name text area or select a name from the drop-down list.

   NOTE: When an anatomic marker is placed on the map, it is also added to the Tools List.

Tape Measure Tool Details

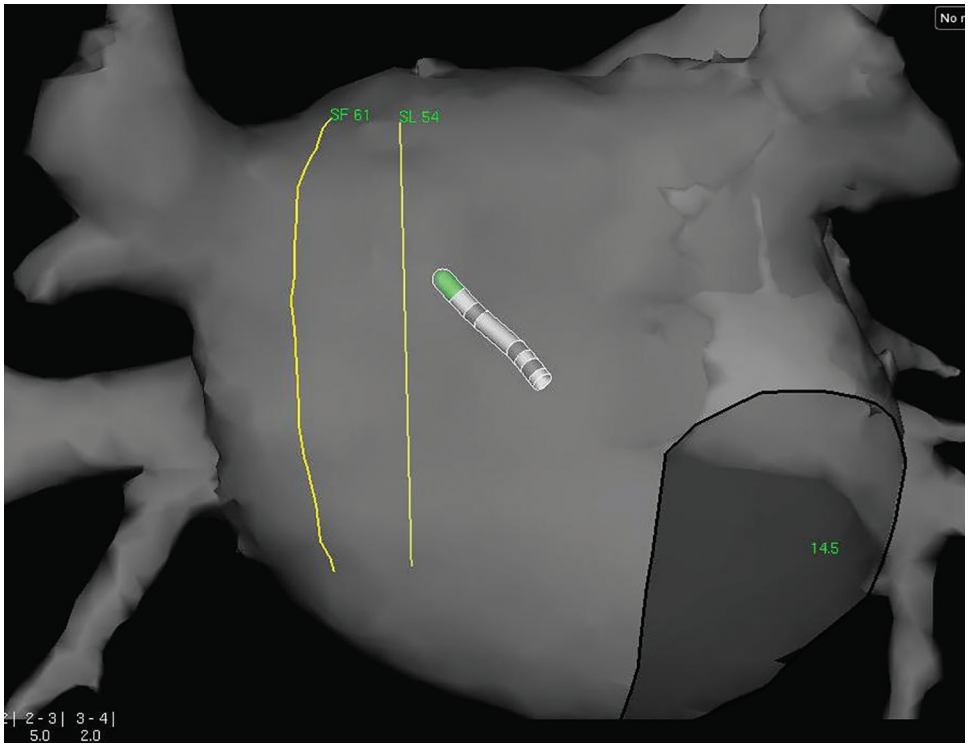
Tape measures are used to measure the distance (in mm) between points on the model of the endocardial surface. The Tape Measure feature may be used with DIF models. Up to 12 tape measures can be placed on the map.

NOTE:

- Tape measure values can only be as accurate as the contoured chamber model that they measure.
- In EnSite NavX™ Mode, Field Scaling must be applied for values to be displayed.

The example below shows a map with two tape measure lines, one across the model surface and one straight line between two model surface locations.

Figure 78. An example of the Tape Measure Tool



Placing a Tape Measure

Select the Tape Measure tool on the Points and Tools Panel.

1. Set the tape measure's color with the Color control on the Points and Tools Panel.
2. Select the desired Type button:
   - Surface radio button – connects two selected points on the map with the shortest possible line along the endocardial surface.
   - Straight Line radio button – connects two selected points on the map with a straight line.
3. Place the tape measure:
   - Select on the map at the point to begin measuring, and then drag the mouse to position the other end of the tape measure.

The tape measure appears on the map as a colored line. The tape measure's type and the distance between the points in mm, appear at the beginning of the tape measure. Up to 12 tape measures (yellow, green, cyan, orange, red, and magenta) can be used.

NOTE: In EnSite NavX™ mode, measurements will not be shown if Field Scaling is not enabled (the line will still show through).

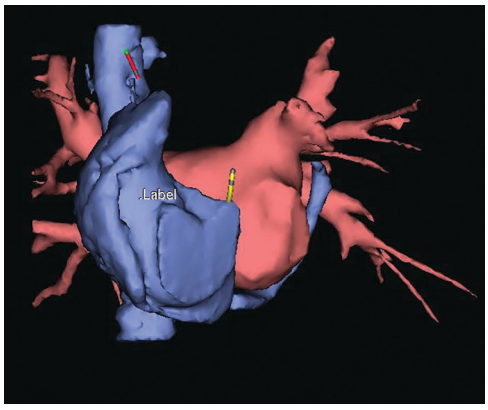
Label Tool Details

Labels are used to identify points on the model. Up to 1024 labels can be placed during a study.

NOTE:

- The labels have no intrinsic meaning to the EnSite™ X EP System. Users can assign their own meaning to labels.
- In EnSite™ VoXel mode, Label at EnGuide(s) can only be placed with Sensor Enabled™ catheter electrodes that are in a high confidence state.

Figure 79. A model with a label displayed



Placing a Label

Select the Label tool on the Points and Tools Panel.

1. Type the label's name in the Name text area on the Points and Tools Panel or select a name from the drop-down menu. By selecting the drop-down menu after a name appears in the text area, commonly used names can be added or removed from the drop-down menu.

   NOTE:

   - Once a label name is automatically added to the list, it cannot be manually removed.
   - The list in the drop down is cleared at the end of each study.

1. Use the Projection slider (text entry box) to set the projection distance if the label is to be projected.

2. Place the label using one of the following methods:

   - Select on the map or DIF surface to place the label at the pointer location. Clicking repeatedly places multiple labels.

   NOTE: When placing labels with the mouse, labels can be placed on either the DIF model or the created model surface. For multiple-surface models, the label appears on the surface beneath the pointer.

   - Select [Label] button to place a label at a point on the surface nearest to the Active Electrode. For multiple-surface models, the label appears on the nearest included surface. Label location is projected from the 3D center of the Active Electrode to the nearest surface. If the surface is edited and the projection distance is exceeded, the label re-projects from the original 3D catheter location, because the original 3D catheter location is preserved.
   - Select [3D Label] button to place a 3D label at the Active Electrode location. This label is not connected to the surface of the map but rotates with the model. This function is useful for labeling the location of catheters outside of the chamber.

   NOTE: When a label is placed, it is also added to the Tools List.

Lesion (Manual) Marker Tool Details

Lesion markers are used to identify ablation lesion marker sites. Up to 1024 lesions can be placed in the map display. Lesion markers are projected from the 3D center of the Active Electrode to the nearest surface. The original 3D catheter location is preserved. If the surface is edited, the lesion is re-projected from the original 3D catheter location.

When using the Lesion Marker tool, the user can place lesion markers with the mouse or use the tool bar to place surface and 3D lesions at the Active Electrode.

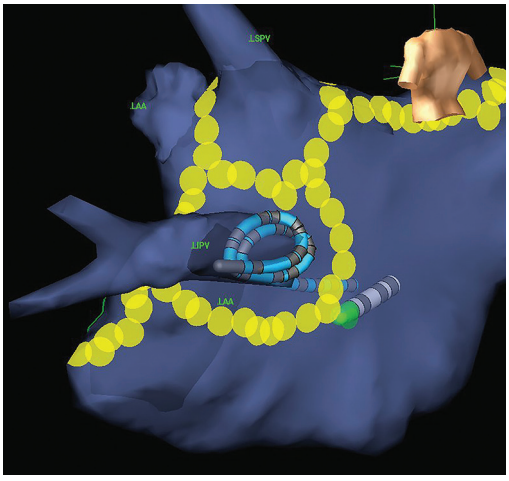
An adjustable distance control allows the user to edit the distance allowed for projection. Lesion markers that are present and do not meet the 3D distance requirement are displayed as 3D objects (without being tied to a surface).

The user has the option to project, or not to project the lesion.

Each lesion marker has a numeric name that is displayed in a list. This number increments each time a lesion marker is placed on the map. If a lesion marker is deleted, the numeric list is updated to keep numbers consecutive.

NOTE: In EnSite™ VoXel mode, Lesion markers can only be placed with Sensor Enabled™ catheter electrodes that are in a high confidence state.

Figure 80. A map with lesion markers on the surface



Placing Lesion Markers

Place the lesion marker using one of the following methods:

1. Click on the map to place the lesion marker at the mouse pointer. For multiple-surface models, the lesion marker appears on the surface beneath the pointer.

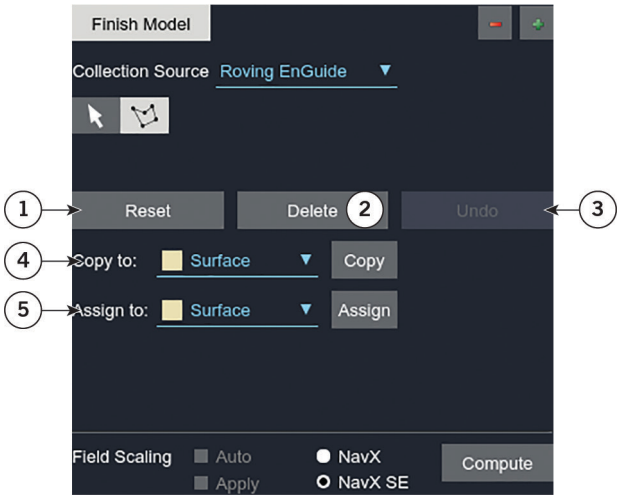
2. Click the Lesion button to place the lesion marker on the point on the endocardial surface that is highlighted by the EnGuide proximity indicator. For multiple-surface models, the lesion marker appears on the nearest included surface. A lesion marker placed with the Lesion button is already projected. To move the lesion marker to the Active Electrode, turn off the Project Selected Lesions checkbox.

   - Hot key: <F6> places a lesion marker at the Active Electrode.

3. Click the 3D Lesion button to place the lesion marker at the Active Electrode. This lesion marker appears as a sphere and is not connected to the surface of the map but rotates with the model. To project the lesion marker onto the closest surface, turn on the Project Selected Lesions checkbox.

   - Hot key: <Shift>+<F6> places a 3D lesion marker at the Active Electrode.

Figure 84. Collect Tab – Model Sub-tab – Edit Model/Select Points mode



Select Points Mode

When the Select Points button is selected, point editing is active. To select points in the selected surface, sequentially click to create a closed loop around the desired points. Once the loop is closed the selected points will be highlighted. These points can then be deleted, assigned to another surface, or copied to another surface.

1. Reset button – Select to reset the point selection in the Model/Map Display.
2. Delete Points button – Enabled once the point selection loop is closed. When enabled, select the Delete Points button to delete the selected points.
3. Undo Delete button – Select this button to undo the delete operation.
4. Copy to drop-down list & Copy Button – Use the drop-down list to choose the desired existing or new surface to copy the selected points. Then select the Copy Button to Copy the selected points to the selected surface. The selected points now appear in the original surface and the newly selected surface.
5. Assign to drop-down list & Assign Button – Use the drop-down list to choose the desired existing or new surface to assign the selected points. Then select the Assign Button to move the selected points from the current surface to the selected surface.

The EnSite™ X EP System Navigation Modes

The EnGuide navigation system is used to display catheters and electrodes. The EnSite™ X EP System provides two primary ways to locate and navigate catheters. The EnSite™ VoXel Mode and the EnSite NavX™ mode.

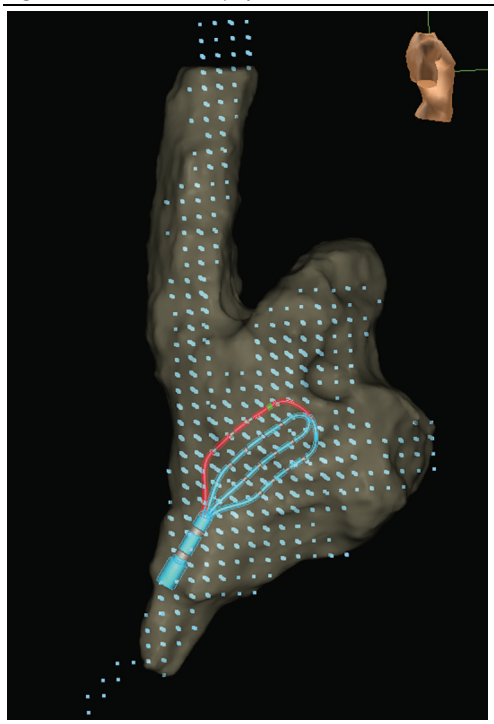
In both navigation modes the maximum number of catheters that can be used simultaneously is 8. The maximum number of electrodes that can be located is 200, and the maximum number of electrodes per catheter is 80. Catheter setup is typically done as a part of the Setup task at the beginning of a study.

EnSite™ VoXel Mode

The EnSite™ VoXel mode can be used to locate, navigate, and collect data from one or more Sensor Enabled™ catheters; standard catheters will be visualized but cannot be used to collect 3D data. In EnSite™ VoXel mode the locations of the catheters are primarily based on the signals generated by Sensor Enabled™ catheters in conjunction with the Field Frame. EnSite™ X Surface Electrode data is used to aid in catheter visualization. Only Sensor Enabled™ catheters may be selected as the Active EnGuide or Roving Source in EnSite™ VoXel mode.

NOTE: The maximum catheter navigation accuracy error is 2.0 mm in EnSite™ VoXel mode.

Figure 85. VoXel Cloud Display



EnSite™ VoXel Mode

VoXels are not limited to the model creation process, rather VoXels are collected at all times. The user may turn visualization of the VoXel cloud on or off at any time. Visualization of the point cloud can aide in showing areas that may require more attention to obtain high confidence catheter visualization.

To enable display of the VoXel cloud, enable the checkbox located in the Map and Display Settings Panel.

If RespComp X is enabled, VoXels are collected continuously.

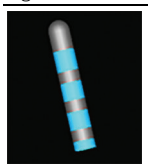
If RespComp X is not enabled, or turned off, collection of VoXels is gated to the end expiration phase.

Sensor Enabled™ Catheter Visualization

VoXels are links between the magnetic and impedance data which allow non-rigid portions of Sensor Enabled™ tools to be visualized and used for data collection. VoXels are automatically created by moving a Sensor Enabled™ catheter within the cardiac anatomy and appear as blue squares in 3D space when turned on by the user. The catheter visualization changes depending on the density of VoXels surrounding each catheter. When the density of VoXels is low, the catheter will show in a low confidence state. When the density of VoXels is high, the catheter will show in a high confidence state. 3D data can be collected from any electrode that is shown which changes based on the confidence state.

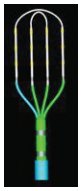
NOTE: VoXels are collected at all times as long as the magnetic and impedance data of the catheter shaft is valid and RespComp X is enabled. VoXel collection is not tied to the Edit Model state or a specific model surface.

Figure 86. Sensor Enabled™ visualization for confidence states



High confidence example: Ablation catheter

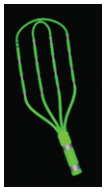
Sensor Enabled™ Ablation catheters are always high confidence and will be visualized showing all electrodes and color as selected by the user.



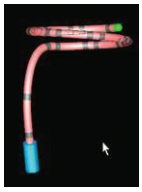
LOW Confidence Example: Advisor™ HD Grid Catheter, Sensor Enabled™

LOW Confidence example: Advisor™ FL and Advisor™ VL Catheters, Sensor Enabled™

Sensor Enabled™ diagnostic catheters have low and high confidence states. If the density of VoXels surrounding a Sensor Enabled™ diagnostic catheter is too low, the Sensor Enabled™ diagnostic catheter will display in the low confidence state. In the low confidence state the electrodes near the magnetic sensor location (on the shaft) will appear as well as the proximal row of electrodes on the Advisor HD Grid catheter. The rest of the electrode will be replaced by a ghost-like shape as seen here. In the low confidence state, 3D data can only be collected from the visible silver electrodes.



HIGH Confidence example: Advisor™ HD Grid Catheter, Sensor Enabled™



HIGH Confidence example: Advisor™ FL and Advisor™ VL Catheters, Sensor Enabled™

Once the density of VoXels surrounding a Sensor Enabled™ diagnostic catheter is sufficient, the Sensor Enabled™ diagnostic catheter will display in the high confidence state. In the high confidence state ALL electrodes on the catheter are visible and 3D data can be collected from all electrodes.

NOTE: If a catheter confidence is low in a region, move the catheter to that area until enough VoXels are collected to obtain high confidence.

Standard Catheter Visualization

Standard Catheters are any catheters that are not Sensor Enabled™. Standard catheters will be visualized but cannot be used to collect 3D data. IEGM data can always be visualized for Standard Catheters. Standard catheters will not be displayed in a region without VoXels. When the density of VoXels is low, the catheter will show in low confidence. When the density of VoXels is high, the catheter will show in high confidence.

NOTE: 3D locations of low confidence Standard catheters are shown for information purposes only. 3D locations should be visualized with an alternate 3D imaging technique.

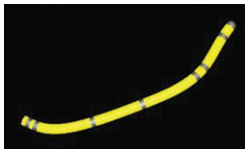
Figure 87. Standard Catheter visualization for confidence states

No catheter shown.

Standard catheters will not be displayed if VoXels have not been collected.

LOW Confidence example: Standard Catheter

Standard catheters have low and high confidence states once VoXels have been collected. If the density of VoXels surrounding a Standard catheter is too low, the catheter will display in the low confidence state. In the low confidence state, Standard catheter electrodes will be replaced by a ghost-like shape as seen here.



HIGH Confidence example: Standard Catheter

Once the density of VoXels surrounding Standard catheter is sufficient, the Standard catheter will display in the high confidence state. In the high confidence state ALL electrodes on the catheter are visible. Although the electrodes are visible, Standard catheters will be visualized but cannot be used to collect 3D data.

Impedance Shift

When an impedance shift is detected in VoXel mode the VoXel collection is suspended. Catheters go into low confidence (shaft electrodes are still in high confidence). A message appears stating that a shift has been detected and VoXel collection will be stopped with the option to 'Close" or "Delete VoXels".

If the user presses "Close" the message will be dismissed for 5 seconds.

If the user presses "Delete VoXels" a new message appears asking: Are you sure you want to delete all VoXels? Model Map Lesions and AutoMarks will not be deleted.

Press the Delete VoXels button for VoXel collection to resume, the catheters go into low/high confidence according to the available VoXels. A message will appear stating that the impedance shift has resolved and VoXel collection has resumed.

EnSite NavX™ Mode

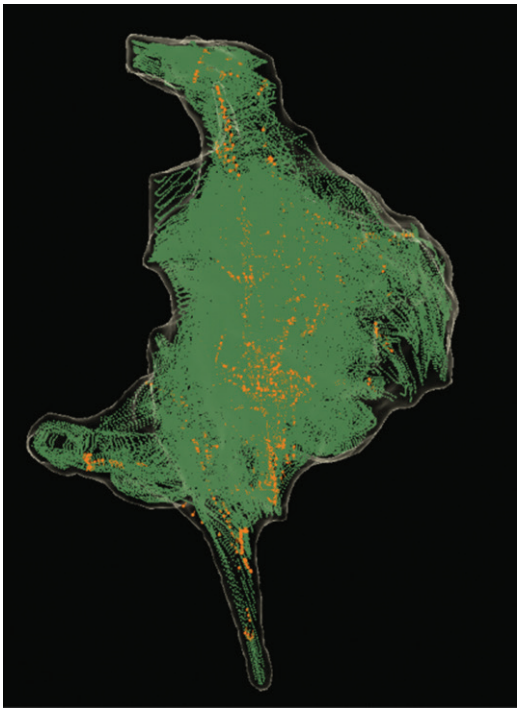
The EnSite NavX™ mode can be used to locate one or more standard EP catheters; Sensor Enabled™ catheters may also be used. In EnSite NavX™ mode the locations of the catheters are primarily based on the signals generated from the impedance measurements of NavX surface electrodes. When using Sensor Enabled™ catheters in EnSite NavX™ Mode, the EnSite™ X EP System collects both impedance-based (NavX) points and magnetic-based (NavX SE) points. Field Scaling can then be applied using either data set to optimize the model.

When using EnSite NavX™ Mode, accurate distance measurements are dependent on application of NavX Sensor Enabled™ Field Scaling. Prior to EnSite™ NavX™ SE Field Scaling being applied, distance measurements are either not shown or are estimated based on the impedance measurements and the user-supplied patient weight. Measurements that become dimensionally accurate with the application of EnSite™ NavX™ SE Field Scaling include:

- Interior Projection
- Exterior Projection
- Interpolation
- Speed Limit
- Distance (AutoMap Threshold)
- Lesion Marker & AutoMark - Diameter
- Lesion Marker & AutoMark - Project on Surface
- Label Tool & Lesion Tool – Projection
- Marker Tools List – Area (Area measurement will not be displayed until Field Scaling is applied)
- Tape Measure – Name (Tape Measure measurement will not be displayed until Field Scaling is applied)

NOTE: The maximum catheter navigation accuracy error is 2 mm in an EnSite NavX™ mode in a Sensor Enabled™ field scaled model.
NOTE: The maximum allowable Tracking Accuracy error in an EnSite NavX™ SE field scaled model is 10%.

Figure 88. Points Display



Example of Edge Enhancement and EnSite NavX™ SE points

1. EnSite NavX™ Mode
2. In EnSite™ NavX™ Sensor Enabled™ points, orange points, are collected from Sensor Enabled™ catheters during model creation. EnSite NavX™ SE points represent the magnetic data within the impedance field. Select the NavX Sensor Enabled™ checkbox to display these points in addition to the green model points.
3. Collect EnSite NavX™ SE points globally throughout the model to ensure an accurate distribution of sensor data within the field.

Looking closely at the EnSite NavX™ SE point pairs, the points are made up of two components:

- The orange sphere, which corresponds to the location of the electrode located within the EnSite™ NavX™ impedance field.
- The tail of the point pair, which points toward the corresponding sensor location.

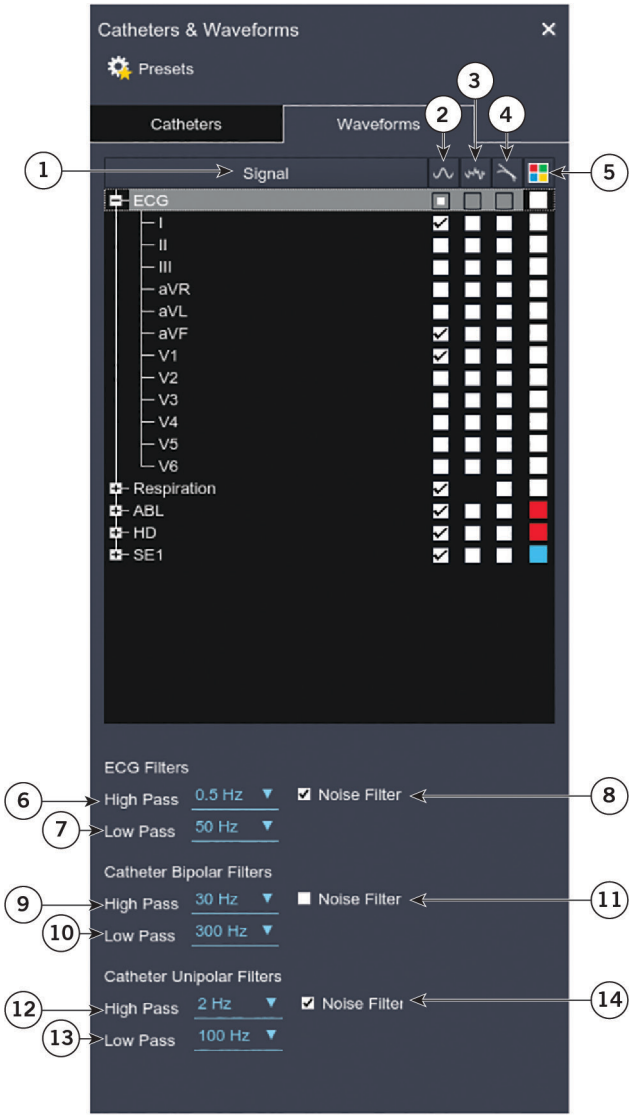
NOTE: EnSite NavX™ SE points are always gated to end expiration of the respiratory cycle.

Setting the Active EnGuide and Active Electrodes

The display of an EP catheter in the model screen display is called an EnGuide. The Active EnGuide and Active Electrode are the catheter and electrode that are used for creating surfaces, placing labels, placing lesions, and collecting points for maps. Only Sensor Enabled™ catheters may be used as the Active EnGuide or Roving Source in EnSite™ VoXel mode. Any catheter may be the Active EnGuide in EnSite NavX™ mode.

The controls for selecting the Active EnGuide and Active Electrode are in the Points and Tools Panel. Use the drop-down menus to change these values. The Active Electrode is green; all other electrodes are silver.

Figure 143. Catheters & Waveforms Panel – Waveforms Sub-tab



1. Signal – Name of displayed signal source
2. Filtered icon – Show filtered signals and waveforms
3. Unfiltered icon – Show unfiltered signals and waveforms
4. dv/dt icon – Show the dv/dt of signals waveforms
5. Color icon – Use the color chart to select a color for the item. Select the colored square to open the color chart, and then select the desired color. Changing the color of a waveform changes the color in the Waveform Display and in the Acquisition Waveform Display.
6. ECG Filters High Pass drop-down list – Use to set the High Pass filter for ECG waveforms.
7. ECG Filters Low Pass drop-down list – Use to set the Low Pass filter for ECG waveforms.
8. ECG Filters Noise Filter checkbox – Use to turn on/off the Noise Filter for ECG waveforms.
9. Catheter Bipolar Filters High Pass drop-down list – Use to set High Pass filter for Bipolar waveforms.
10. Catheter Bipolar Filters Low Pass drop-down list – Use to set Low Pass filter for Bipolar waveforms.
11. Catheter Bipolar Filters Noise Filter checkbox – Use to turn on/off the Noise Filter for Bipolar waveforms.
12. Catheter Unipolar Filters High Pass drop-down list – Use to set High Pass filter for Unipolar waveforms.
13. Catheter Unipolar Filters Low Pass drop-down list – Use to set Low Pass filter for Unipolar waveforms.
14. Catheter Unipolar Filters Noise Filter checkbox– Use to turn on/off the Noise Filter for Unipolar waveforms.

Model, DIF & Fusion Settings Panel

The Model, DIF and Fusion Panel provide access to Model Surface presets and DIF & Fusion functionality.

Model, DIF & Fusion Panel - Model Sub-tab

The Model tab allows provides the ability to define or change a Surface preset or surface details. The addition or deletion of surfaces is available on the Collect Panel - Model Sub-tab.

Model presets are used to initialize a model using a predefined list of surfaces. When a model preset is loaded, the surfaces do not exist, but they have properties such as names and colors. This list can serve as a starting point for which surfaces to collect points. Refer to the Model, Diff & Fusion Settings Panel to load and manage Model presets.

NOTE: Areas marked with a yellow border are values saved with a preset. These values change in all corresponding areas of the user interface.

1. Low-V ID slider – (Applies to the map that has focus when in Split Screen mode.) Identifies low-voltage zones in LAT or CFE maps. If a collected point's P-P value is lower than the specified Low-V ID value, then that point will display a gray area instead of the color- coded scale for the current map type. Grey points do not interpolate with color points.
2. Fractionation Threshold checkbox/slider – Renders points that are fractionated as larger spheres. Default value=3 (renders points with a fractionation value of >= 3.
3. Map Display – (LAT maps only) The type of LAT map: Standard LAT, Reentrant Map, Full-Color Propagation or Propagation Map.
4. Sparkle Map button – Displayed the activation sequence overlaid on top of another map. The SparkleMap shows the propagation sequence using a series of circular flashes. The button changes to "Stop" while Sparkle Map is playing and will stop Sparkle Map when selected. The speed that the Sparkle Map is played is controlled by the drop-down next to the button. Sparkle Map button is unavailable when the Map Display control is set to either type of propagation map.
5. Interior Projection slider – (Applies to both maps when Split Screen mode is active.) This slider controls the maximum distance that an interior 3D Point (represented as a triangle) can project to a location on the surface (represented by a square). For multiple-surface models, points will project to the nearest surface.
6. Interpolation slider – (Applies to the map that has focus when in Split Screen mode.) This slider controls the minimum distance between surface points necessary for the system to interpolate color. For multiple surface models, points will interpolate between surfaces in the same group.
7. Surface Points checkbox – (Applies to the map that has focus when in Split Screen mode.) Enables/disables the display of small square points on the surface. These squares represent the point on the surface closest to a collected 3D point.
8. All roving Waves checkbox – Select to display all roving waves. When deselected, only one roving wave is displayed in the Acquisition Waveform Display.
9. 3D Points checkbox – (Applies to the map that has focus when in Split Screen mode.) Enables/disables the display of collected points as triangular markers. The triangular markers are placed on the negative electrode of the roving signal channel.
10. Unipole waves checkbox – Select to display unipolar waves of the roving signals in the Acquisition Waveform Display.
11. REF and ROV tabs – this area will be described in later sections.
12. Score checkbox/slider – Score Threshold: Full or any combination of the 12 Surface Leads. Only collect mapping points if the 12-Lead Surface Morphology is XX% similar or higher compared to the original template beat 12-Lead Surface Morphology. The user can set the Score Threshold from 0 to 100%. By default, the Score Threshold is enabled and is set to 90%.
13. CL Tolerance checkbox/slider - Cycle Length Tolerance: Only collect mapping points if the intracardiac measured (CS, HIS, other) Cycle Length is within +/- XX ms of original template beat Cycle Length. User can set the Cycle Length Tolerance from +/- 0 to 150 ms. Default the Cycle Length Tolerance is enabled and is set to +/- 20 ms.
14. Activation Seq checkbox/slider – Activation Sequence is defined as the timing between the primary reference (REF) detection and the secondary reference (REF 2) detection when both the REF and the REF 2 are set to intracardiac signals. Mapping points when the Activation Sequence of the current beat is within +/- XX ms of the template beat Activation Sequence. The user can set the Activation Sequence tolerance slider from +/-0 to 25 ms with a default of +/- 5 ms.
15. Speed Limit checkbox/slider – Speed Limit: Only collect mapping points if the mapping catheter is moving less than XX.X mm/s. User can set the Speed Limit from 0.1 to 75 mm/s. Default the Speed Limit is enabled and is set to 10.0 mm/s.
16. Distance checkbox/slider – Distance Threshold: Only collect mapping points if the 3D position of the roving catheter electrode is X.X mm or more from the previously collected mapping point from that electrode. User can set the Distance Threshold from 0.1 to 10 mm. Default Distance Threshold is enabled but the default value is set to 1.0 mm.
17. Signal to Noise checkbox/slider – SNR Threshold: Only collect mapping points if the Signal-To- Noise Ratio on the roving catheter signal is X.X or higher. User can set the SNR Threshold from 1 to 50. Default the SNR Threshold is enabled and is set at 5.0.
18. Force checkbox/slider – Force (Contact Force Range): This criteria can only be used if the EnSite™ X Contact Force Module is installed and the physician is mapping with a TactiCath™ catheter. Only collect mapping points if the Average Contact Force (as measured by a TactiCath™ Contact Force Catheter) is at least X grams and less than Y grams. User can set the Lower Threshold from 0 to 30 grams. User can set the Upper Threshold from 30 grams to 150 grams. Default the Contact Force Threshold is not enabled but the default lower threshold is 10 grams and the default upper threshold is 50 grams.
19. Enhanced Noise Rejection checkbox – Enhanced Noise Rejection: Only collect mapping points if the roving catheter signal does not have certain types of noise (Signals with saturations, electrode-to-electrode contact, open electrode noise, signals with degraded conditions such as no location or dropped data). Only uncheck for pace mapping. User can set the Enhanced Noise Reduction on or off. Default the Enhanced Noise Reduction is enabled.

AutoMap Description

The AutoMap feature automates the point collection process, based on the user-defined settings. As the catheter is moved, points are collected when the user-defined settings are met.

Figure 105. Mapping Screen

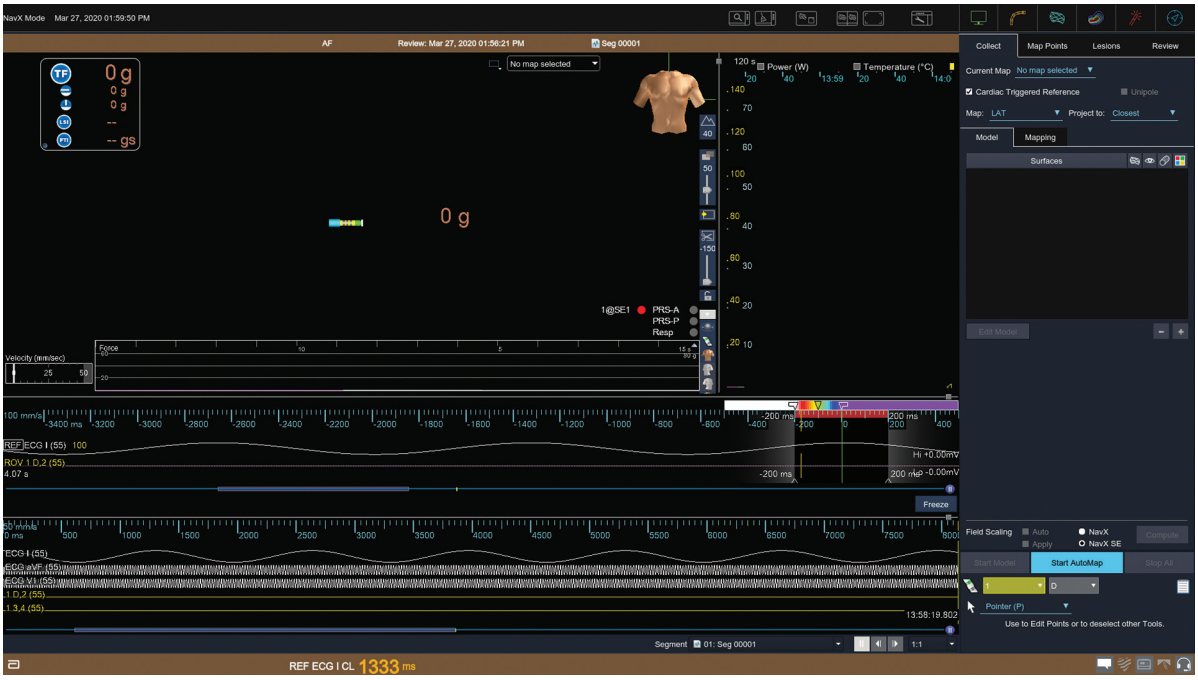
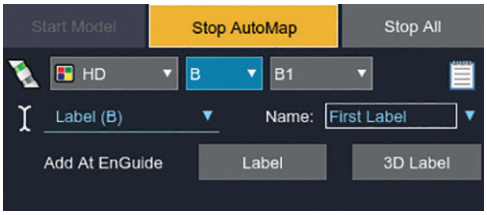


Figure 106. Start/Stop Automap



Start AutoMap/Stop AutoMap button: Select to begin automatic mapping point collection — select again to stop automatic mapping point collection.

Stop All button: Stops automatic mapping point collection AND stops anatomic model point collection.

The user can also start/stop the AutoMap feature by using shift+F11 key.

AutoMap Settings

AutoMap Settings define the minimum criteria that must be met for a mapping point to be automatically collected. Select the box next to each criterion to be used for automatic point collection. The settings for AutoMap differ between cardiac and non-cardiac triggered references.

Point Collection Status Meter

The point collection status meter provides feedback on whether the AutoMap threshold criteria are being met during point collection. To view this meter in the model/map display, select the Point Collection Status checkbox in the Meter & Display Options settings panel.

- White when viewing data in real time.
- Gold when viewing data in review mode.
- Brown when mapping point is frozen or selected.
- Red when AutoMap threshold criteria associated with metric are not being met.
- Purple when a frozen or selected mapping point contains unreliable data.
- Purple dash when:
  - the reference detection is degraded for the current beat or previous beat or
  - the previous detection beat does not exist due to clearing the beat buffer.

Score Map

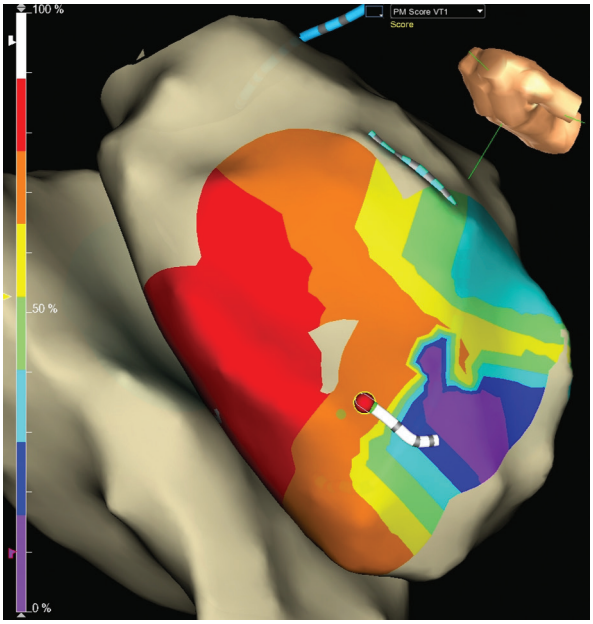
A Score Map is a map type that plots the surface lead morphology match score associated with each mapping point collected compared to the originally collected template beat surface lead morphology. The physician may want to use this feature during pace mapping where it may be useful to plot the 90%-100% morphology match scores in the area of interest.

The user may also sort the points list by score from highest score surface lead morphology match compared to the template beat to lowest score surface lead morphology match compared to the template beat. When the user clicks on the mapping point, they will be able to view the current mapping point surface lead morphology on top of the template beat surface lead morphology trace. This may be useful to determine which surface lead(s) are different from the template beat.

It is possible to adjust the map scale to only display the 90-100% matches on the map.

The Score Map can also be used during automated mapping to allow users to automatically collect only those points with morphology match scores that are XX% similar or higher compared to the template beat and automatically reject those points that are not XX% similar or higher compared to the original template beat.

Figure 110. Score Map Example



When Start AutoMap is activated, the software automatically records the data from 10 seconds before the EnSite™ X AutoMap feature was activated and continues recording as long as the EnSite™ X AutoMap feature is active.

TurboMap

Once original mapping has occurred, the user may change mapping criteria and play back through the original dataset at Max speed to generate a new map at 10x's real-time speed. This is called the TurboMap feature. As an example, if the original mapping time was 10 minutes, the user can generate a second map in only 1 additional minute. This same concept can be employed for multiple maps. This may be useful if the physician is mapping Sinus Rhythm and intermittent, multiple PVC or VT morphology beats are occurring. This may also be useful if the physician is trying to map multiple, distinct Cycle Length atrial tachycardias.

Figure 111. Playback Speed Selection Menu

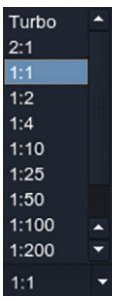
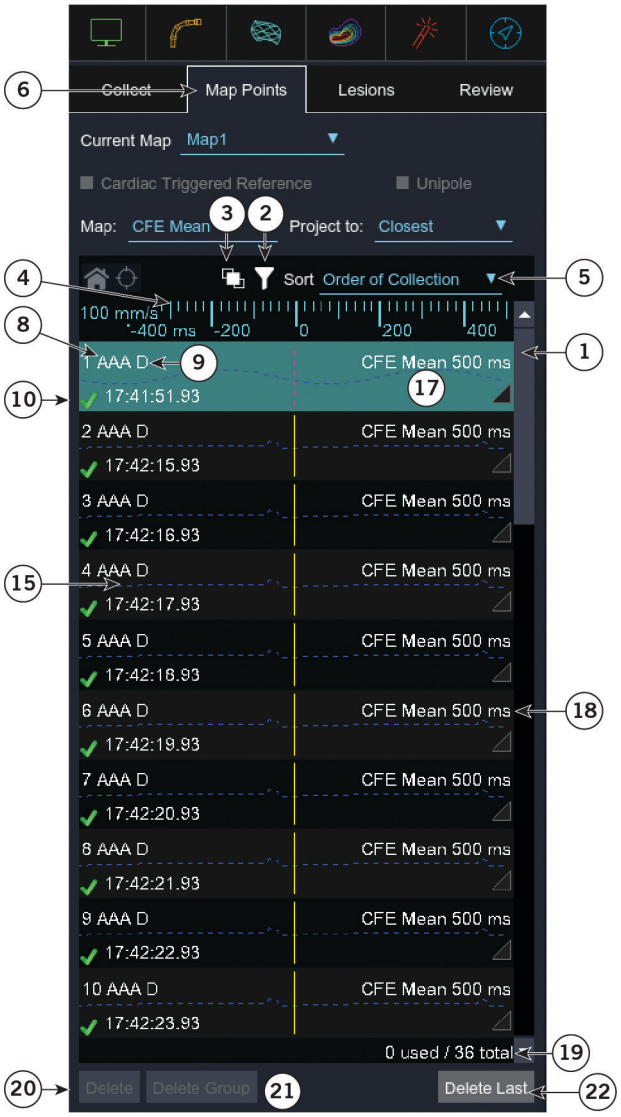


Figure 116. Map Points Workpanel (Points list and point display options)



1. Scroll to Selected icon – Scrolls the list to the selected point.
2. Locate Point icon – Locates the selected point in 3D space.
3. Show Duplicate of Selected icon – Show duplicates of the selected point.
4. Show/Hide Unused Points icon – Show all points or only the used points.
5. Sort drop-down list – Sort waveforms by order of collection, current map type, and cycle length. (After making timing adjustments, the user must select sort by LAT again.)
6. Map Points list – Displays the list of points saved to the current map.
7. Timescale: The time scale, in milliseconds (ms), displays at the top edge of the waveform display. The timing reference of all waveforms is synchronized to 0 msec. Adjust the Sweep Speed by right-clicking in the black background and selecting Sweep Speed. The available options are 40, 50, 100, 200, and 400 mm/sec.
8. Waveform Number - Indicates the order of waveform collection. When multiple points are acquired simultaneously, all the related points have the same waveform number.
9. Electrode Polarity - Polarity of the electrodes on the catheter. Unipolar is indicated with the single electrode preceded by a "+" sign.
10. Hide Point Checkbox - When checked, this checkbox indicates that this point on the map may show. Clear the check mark to hide this point. When unchecked, the point is hidden, and a red circle displays.
11. Duplicate Points - A star above the check box indicates a duplicate point. There are 3 types of duplicate points:
    - Blue outline star - duplicate point, but not used
    - Solid blue star - point has duplicates, but this point is used by the system
    - Solid gold start - point has duplicates, but the user chose to use this point
1. Dashed Waveform Line - A dashed waveform line indicates that a point is not used to color the map (not shown). The following types of points are drawn as dashed: hidden points, duplicate points, points outside the projection distances, and points with no locations.
2. Solid Waveform Line - Indicates a point that is used in the map.
3. Blue background - Indicates the selected waveform. The data for the waveform is shown in the waveform display. If the corresponding point is used in the map, the 3D point, its projection on the map surface, and its text, flash red.
4. Map point measurement - The Timing (in ms) or Voltage (in mV) of the map point.
5. Number of points - The number of points that have been selected/used/collected. The list may have to be scrolled to see all the waveforms.
6. Delete button – To delete a waveform from the Points display and its corresponding point from the map, select the waveform and select [Delete].
7. Delete Group button – Removes the selected group of points.
8. Delete Last button – Removes the selected group of point(s) last saved.

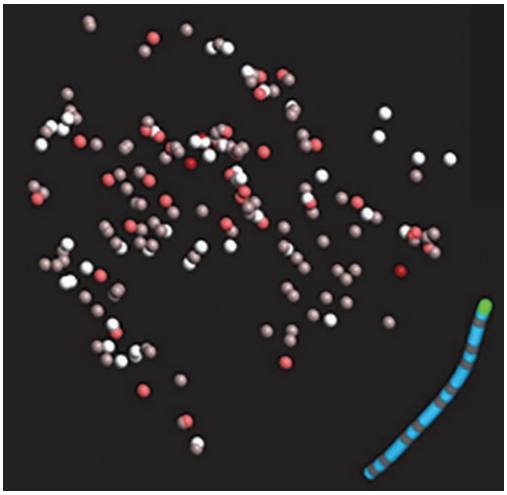
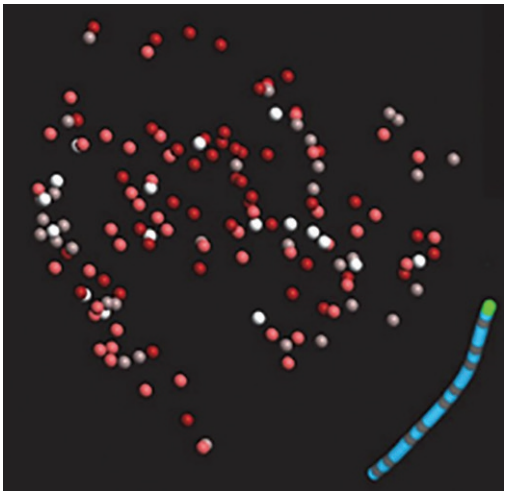
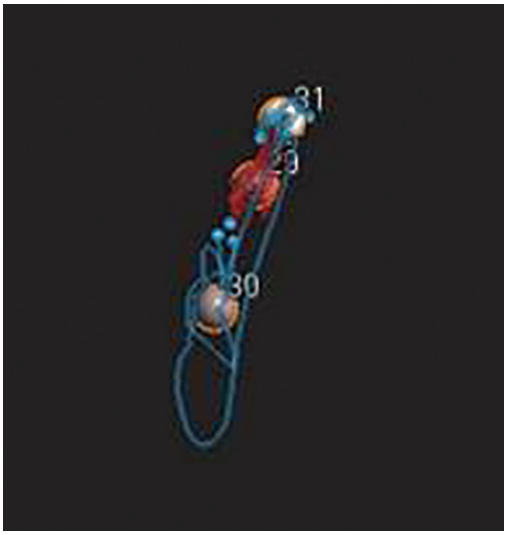
Amplitude – Waveform amplitude can be adjusted by middle-clicking the waveform and dragging up or down. For the Points display, amplitudes are ganged for all waveforms.

Panning – The Points display will default to centering on the timing reference. The display can be panned by <Shift> + middle- clicking in the background and dragging left or right.

Waveform indicators – The type of line used in the waveform indicates the effect of the waveform on the map.

- Solid, bold with blue background – The waveform is selected. The original data for this waveform is currently displayed in the waveform display. If displayed in the map display, the 3D point, 3D text, and surface point for this waveform flashes red.

Table 5. AutoMark Placement Examples

Example 3 Away Time: 8 s Min AutoMark Time: 3 s AutoMark Region: 5.0 mm	Example 4 Away Time: 8 s Min AutoMark Time: 3 s AutoMark Region: 2.5 mm
	
More AutoMarks are created because the spacing between AutoMarks is only 0.5 mm (instead of 1.5 mm). Additionally, the AutoMarks tend to have a lower corresponding time as only data within the 0.5 mm region is collected.	Fewer AutoMarks are created because the spacing between AutoMarks is 2.5 mm (instead of 1.5 mm). Additionally, the AutoMarks tend to have a higher corresponding time as data within the 2.5 mm region is collected.
Example 5 Away Time: 8 s Min AutoMark Time: 3 s AutoMark Region: 1.5 mm	Example 6 Away Time: 2 s Min AutoMark Time: 3 s AutoMark Region: 1.5 mm
	
AutoTrack shows larger catheter movement for each AutoMark because all catheter movement resulting from respiration motion is included in the AutoMark data.	AutoTrack shows smaller catheter movement for each AutoMark because less catheter movement resulting from respiration motion is included in the AutoMark data due to the shorter Away time.

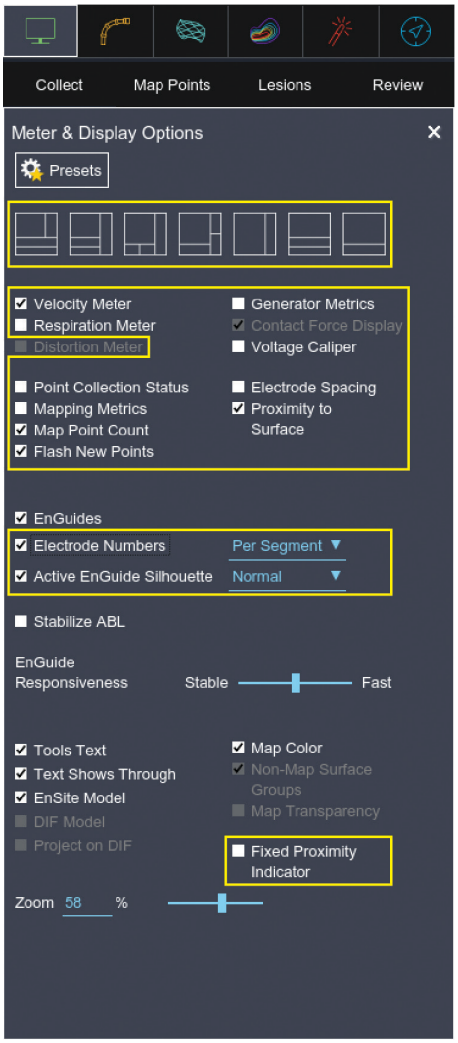
Settings Panels

The Settings Panels contain controls and settings less often modified during a case. Presets can be managed from the settings panels and are context sensitive. When the user is within any specific Settings Panel, the user may manage the presets for that Settings Panel only. The contents of a Settings Panel temporarily displays in the Work Panel space when an individual control is accessed. Panels are minimized using the 'Close' icon, or when another panel icon is selected. Once Settings Panels are closed, the Work Panel returns to view.

> NOTE: Areas marked within a box are settings and values saved with a preset. The example below shows the Meter and Display Options settings panel. All items within a box will be saved as a preset. These values change in all corresponding areas of the user interface (Work Panels, Settings Panels and the Mobile Work Panel.).

Not all settings captured in a preset are configured or displayed in panels including display size and location of screens and/or meters/metrics, font sizes, Waveform amplitude, RAI screen, etc.

Figure 140. Settings Panel Preset Options



Study Presets

The use of study presets enables a user to quickly and easily setup a new study with a set of settings that is consistently used for studies. Users can enable or manage presets from the Settings Panels in the Workspace (Catheter presets can also be enabled in Setup.).

Changes made on the Work Panel are reflected on the corresponding Settings Panel. To Save the changes the user must go to the corresponding Settings Panel and save.

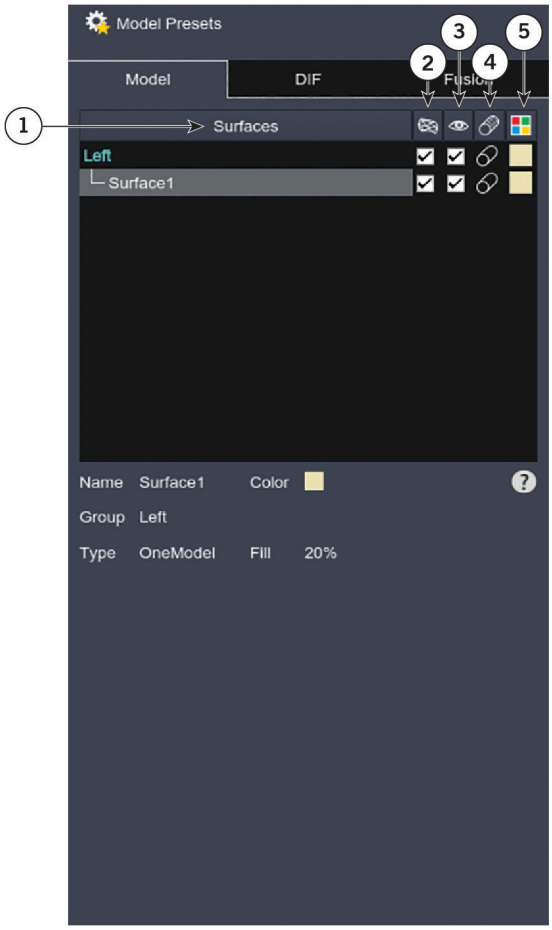
Although there are some differences in the use of presets in these three areas, the basic ideas in their use are the same.

Typically, a user will enable one or more presets at the beginning of a study to save time and avoid manually changing options and settings; rarely are presets changes during a study. One exception is the preset for "Meters & Display Options". This preset may be used to setup the workspace for the different stages of a study (Mapping vs. Therapy) or to configure the display of screens for split-screen viewing or saving images.

When a preset is enabled, options and settings update for all corresponding values in the Work Panels, Settings panels and the Mobile Work Panel.

Preset Dropdown Menu	Save Preset	Manage Preset
Preset Button: The Presets drop-down menu is used to load a preset, save a preset, and manage presets. **To Use Default or Factory Settings Presets:** Select Nominal from the Preset drop-down	**To Save a Preset:** To save the current setup as a preset, open the Preset menu in the upper- left corner of the control panel and select Save Preset. In the Save Preset screen, type a name for the preset, and	**To Rename a Preset:** To rename the preset, double-select the name then enter the new name or select the preset to be renamed then select Rename. **To Delete a Preset:**

Figure 144. Model, DIF& Fusion Panel – Model Sub-tab



1. Surfaces – List of model surfaces
2. Included icon – Select a checkbox to include a surface. Deselect a checkbox to not include a surface. A surface that is not included is not displayed, used for labeling, or intersecting overlapping surfaces.

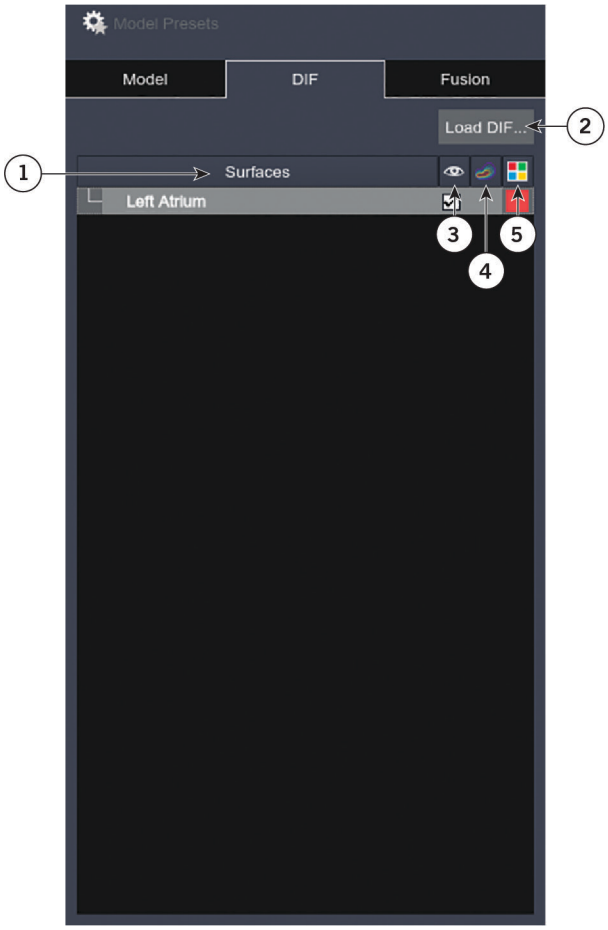
   NOTE: Excluding unnecessary surfaces optimizes performance. This checkbox controls whether a surface is displayed in the model. When the check mark is visible, the surface is displayed for labeling, intersecting, and overlapping surfaces. When the checkbox is unchecked, the entire surface is excluded from view.
3. Visibility icon – Use the visibility icon to show or hide the item. When the checkbox is selected, the item is visible. To hide the item, select the checkbox. Hiding an item does not delete the item.
4. Grid Control icon – The number of clicks (1, 2, or 3) on cylinder will determine where a surface grid is placed on the model. Clicking once, places the grid on the interior of the model, clicking twice, places the grid on the exterior of the surface. Clicking a third time turns the grid off.
5. Color icon – Use the color chart to select a color for the item. Select the colored square to open the color chart, and then select the desired color.

Model, DIF & Fusion Settings Panel - DIF Sub-tab

The DIF list shows both surfaces and associated maps as defined in the EnSite™ Verismo™ Segmentation Tool or the third-party application.

NOTE: There are no Presets for the DIF sub-tab.

Figure 145. Model, DIF& Fusion Panel – DIF Sub-tab



1. Surfaces – List of surfaces
2. Load DIF – Select to load a DIF file.
3. Visibility icon – Use the visibility icon to show or hide the item. When the checkbox is selected, the item is visible. To hide the item, select the checkbox. Hiding an item does not delete the item.
4. Map icon – Use the Map icon to show or hide the DEMRI map if one is imported.
5. Color icon – Use the color chart to select a color for the item. Select the colored square to open the color chart, and then select the desired color.

Digital Image Fusion (DIF)

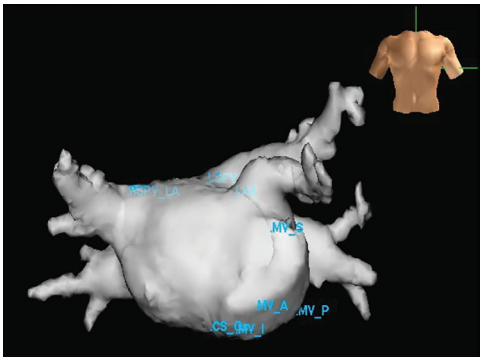
- Three-dimensional models created from digital images collected from Spiral CT, MRI, and DEMRI (Delayed Enhancement MRI) can be imported into the EnSite™ X EP System for display.

Creating a Model to Import

Models for import into the EnSite™ X EP System can be created using segmentation tools such as the EnSite™ Verismo™ Segmentation Tool. When using the EnSite™ Verismo™ Segmentation Tool, the creation of a model involves the following steps.

- The patient is scanned. See the EnSite™ X Verismo™ Segmentation Tool section (page 152) for the optimal EnSite™ X Verismo™ Segmentation Tool scan file characteristics.
- The scanned image is exported to a CD/DVD in DICOM3 format.
- The CD/DVD is imported into an EnSite™ X Display Workstation (DWS) with the EnSite™ Verismo™ Segmentation Tool, and the segmentation process is used to create a DIF file according to the EnSite™ Verismo™ Segmentation Tool Instructions for Use.

Figure 146. An imported DIF left atrium



If the DIF file is created on the same EnSite™ X EP System DWS that will be used during the clinical study, the DIF file can be accessed from the hard drive. If the DIF file will be used on a separate EnSite™ X EP System, the DIF file can be exported to a USB device, network, or CD/DVD for import into the clinical EnSite™ X EP System.

- In addition to the DIF file format, the EnSite™ X EP System also supports CardEP file format for digital images, as well as Siemens, Phillips, Toshiba (Vital Images), and Terra Recon formats; however, formats other than DIF may not be able to use all DIF-related functions, such as the ability to show or hide individual chamber surfaces.

Importing a Digital Image

1. Click the DIF icon at the top of the Model control panel.
2. From the DIF control panel, select Load DIF.

   The Import DIF window appears.
3. From the Load DIF window, select a DIF file for import: select a source, either hard drive or DVD/CD, for import from the drop-down menu at the top right corner of the window.
   - HardDrive – DIF files created by the EnSite™ Verismo™ Segmentation Tool on the same EnSite™ X EP System DWS are stored on the workstation's hard drive. As additional models are added, the oldest models are deleted first. Models can also be manually deleted by selecting a model from the list and selecting Delete.
   - DVD/CD – Digital image models can be imported using DVD and CD. Models can be formatted as Digital Image Fusion (.xml), or GE DICOM3 models processed using CardEP software. For GE CardEP models, the original CD/DVD from the GE workstation is required for import, not just the file of the model itself. Select an image type to display the appropriate models.

Select Load to load the model.

NOTE: The colors applied to the DIF model are the EnSite™ X EP System software model colors, not the colors that were used during segmentation.

Additional Options for DIF Files

Models created by the EnSite™ Verismo™ Segmentation Tool have additional features:

Patient information – In the Import Digital Image window, models are displayed with information from the patient, scan, and saved model name. Clicking on the category name at the top of a column sorts the data by that column.

DIF viewer – A viewer is available for previewing DIF models. Select View to display the selected DIF model. The following controls are available in the viewer:

- Rotate – Hold down the middle mouse button and drag.
- Zoom – Use the roller wheel on the mouse.
- Wireframe – Options > Wireframe.
- Bounding box display – Options > Bounding Box.
- Default views – Views > AP/PA/LL/RL/CRA/CAU.

Viewing a DIF Image for Reference

DIF models can be shown by selecting the DIF Model checkbox in the Meters and Display Options Settings Panel. Deselect to hide the DIF Model.

- The digital image appears in the map display.
- To compare the two models, select Dual View. The EnSite™ X EP System model appears on the left side of the screen, and the DIF model appears on the right side of the screen.

Digital images are saved with rotational information included. The orientation reference will automatically appear for the digital image.

In an EnSite™ X System study, the EnSite™ model and DIF model rotate together when the system is validated.

NOTE: Clipping, Map Scale, rotation, spin, Edge Enhancement, and panning can be used to change the appearance of the model.

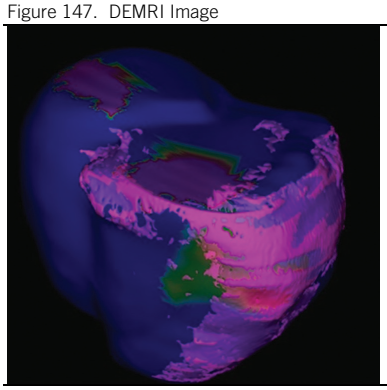
DEMRI (Delayed Enhancement MRI) Image Integration

The use of delayed enhancement MRI is sometimes used to analyze areas of electrically nonviable tissues such as areas of fibrosis, scar, or ischemia. The import of this model type into the EnSite™ X EP System may provide a faster, higher resolution of substrate over traditional voltage mapping. The system can now accept Visualization Tool Kit files, or VTK files, and Visualization Toolkit Polygons, or VTP files. These files are created from a third-party application rather than through the EnSite™ Verismo™ Segmentation Tool.

Once imported, interaction is like a DIF file, with options to view or use with the EnSite™ Fusion™ Registration Module. The DIF list shows both surfaces and associated maps as defined in the third-party application. The color spectrum bar on the left is displayed just as it is for timing and voltage maps within the system. One map tool data set can be displayed on the surface at a time.

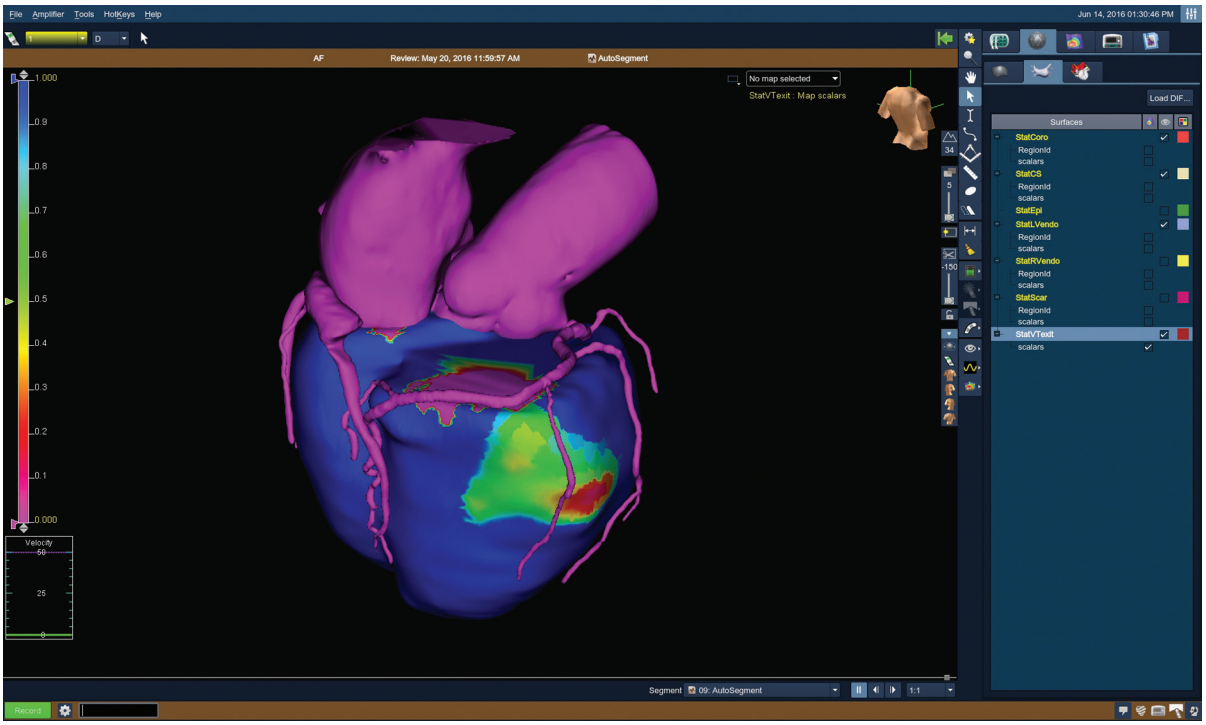
NOTE: If using this model in the EnSite™ Fusion™ Module's registration process in single map display, the user will be able to either visualize the associated imported map or project a contact map on the surface, but not both.

Figure 147. DEMRI Image



In Split Screen view, the user can display an EnSite model in one screen and the DEMRI in the other.

Figure 148. Imported DEMRI Image



File limitations for VTK or VTP files include:

- Total number of vertices cannot exceed 1,000,000.
- Total number of polygons cannot exceed 2,000,000.
- Polygons are limited to only containing three points (triangles).
- Only one occurrence of the <Piece> tag is supported.

Selecting and Adjusting the Waveforms

Waveforms can be selected and adjusted by clicking on the waveform in the waveform display.

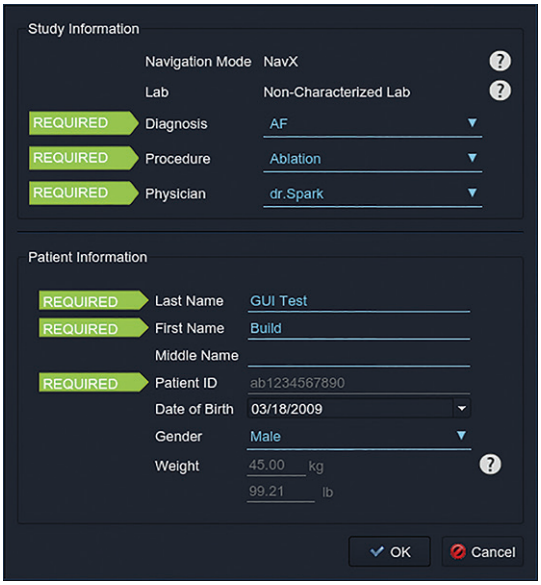
- Selecting waveforms: Shift-left-clicking on a waveform makes the selected trace bold and displays a dotted white line at 0 mV. The color calipers are rail lines indicating the current Color High and Color Low values. Shift-left-click on a waveform again to remove the rail lines and color calipers.
- Moving waveforms: To move a waveform, left-click on the waveform and drag up or down.
- Adding waveforms: To add a waveform to the waveform display, turn on the waveform's checkbox in the Catheters & Waveforms Settings Panel - Waveforms Sub-tab.
- Removing waveforms: To remove a waveform from the waveform display, turn off the waveform's checkbox in the Catheters & Waveforms Settings Panel - Waveforms Sub-tab, or left-click on the waveform and drag it off the left edge of the screen.
- Adjusting amplitude: To adjust the waveform amplitude, middle-click the waveform and drag up or down to increase or decrease the amplitude for all waveforms of that signal type. To adjust the amplitude for a single waveform, hold <Shift> + middle-click and drag up or down.
- Right click in the black background for waveform options menu:
  - Sweep Speed: Adjusts the number of mm/sec. in the waveform display (time scale).
  - Reset Offsets: Evenly spaces all visible waveforms vertically in the waveform display, without changing the order of the display.
  - Reorder Waveforms: Rearranges the waveforms according to the trace number and types as defined by the order in the Catheters & Waveforms Settings Panel - Waveforms Sub-tab.
  - Font Size: Used to select a font size for the label text in the waveform display.
  - Thickness: Used to adjust the thickness of all waveforms in the waveform display.
  - Hi/Lo Lines: Doing a shift-left-click on a selected waveform, causes the waveform to bold and for color calipers to display. The color calipers are horizontal rail lines that indicate the current Color High and the current Color Low values of the selected waveform. Doing a shift-left-click again will remove them.

Using the Waveform Displays

The two types of waveform display windows in the GUI are shown below:

1. Waveform Display.
2. Acquisition Waveform Display.

Figure 162. Study and Patient Information screen.



1. From the top bar, select File > End Study. The system will prompt the user with "End the current study? Yes/No." Select Yes. If study and patient information has already been specified, go to step 3.
2. If study and patient information has not been specified, the system will prompt the user with "Cannot end study without entering study and patient information. Enter study and patient information? Yes/No." Select Yes. The system will display the Study and Patient Information screen. Fill in the required information and Select OK.
3. The system will prompt the user with "Remember to backup study information".
4. Select OK to continue.
5. The system will return to the Login screen.

NOTE: To backup, or archive, the study, see "Archiving Studies".

Capturing, Exporting, and Importing Information

Exporting Data to External Devices

Images and study data can be stored to a USB device, a network drive, or CD/DVD. Compatible CD/DVD formats are: CD-R, CD+R, CD-RW, CD+RW, DVD-R, DVD+R, DVD+RW, and DVD-R Dual Layer.

NOTE: CD/DVDs must be handled with care. Do not allow a CD/DVD to fall on a hard surface. To label a CD/DVD, never use a paper label, always write directly onto the CD/DVD using a permanent marker.
NOTE: Information can only be exported to a CD/DVD from outside of a study.
NOTE: A CD/DVD may contain multiple images, but only one study.
NOTE: If export to a USB device fails, try an alternate external storage device, a network location, or CD/DVD.
NOTE: Network File System (NFS) versions prior to NFSv3 may experience limitations to the addressable file system size to less than 4.2GB. (This is a protocol limitation.)
NOTE: File system access errors may be experienced when using Server Message Block (SMB) versions prior to 2.0. Some files may become inaccessible.
NOTE: USB devices having FAT32 file systems may be unable to store Velocity studies, due to the number of files, file name length, or file size limitations of FAT32. NTFS or ext3 file systems are recommended to be used.

When images are stored to external media, they are listed by their annotation and an index number to differentiate duplicate annotations. Images are stored as JPEG files.

Selecting an Area for Capture

When capturing images or creating animations, the entire screen or a selected area of the screen can be captured. In addition, the images and animations can be captured with a white background. The user specifies what is to be captured in the Capture Image, Record Movie, and Capture Images windows.

- To capture the entire screen, select Full Screen.
- To define the area of the screen to be captured, select Selected Area. To define the area to be captured, Click and hold down the left mouse button and drag a box around the desired area of the screen. Adjust the box if necessary.
- To capture the entire screen or selected area with a white background, select White Background. A white background is beneficial if the images are going to be printed on a printer.

When the desired area has been selected, click [Capture Image] to capture an individual image, or click [Start] to capture an animation. The captured image or animation is stored in the Notebook.

NOTE: Individual images can be captured at any time during a study.
NOTE: MPEG and JPEG animations can only be captured in Offline Review.

Saving and Accessing Individual Images

Images of entire screens can be saved. These images can also be viewed.

Saving an Image

To save an individual image:

1. Select File > Save Image to display the Capture Image window.
2. Type a description of the image in the text area.
3. Indicate the screen area to be captured:
   - Select Full Screen to capture the entire screen.
   - Select Selected Area to manually select the screen area to capture. Refer to “Selecting an Area for Capture” for more information about selecting the screen area.
4. Select White Background if a white background is desired.
5. Click [Capture Image]. The image is captured and saved as a part of the patient study and is added to the Notebook.

Accessing an Image

NOTE: Images are saved with their appropriate study. If a study containing images created in Offline Review mode is removed from the workstation hard drive, the images are removed as well. Be sure to backup studies so the images are saved.

1. Access the Notebook in the Review work panel.
2. Select an annotation from the list. Use the buttons described below to view or manage image files:
   - [Load] displays the image.

   NOTE: This is the only location where printing can be done.

   - [Delete] erases the selected image.
   - [Edit] allows the user to edit the annotation of the image.
3. Click [Close] to exit the window.

Creating Animations

NOTE: Offline Review Mode only.

A series of continuous images of the entire screen can be exported from the system as either an mpeg movie file or a sequence of jpeg images.

Creating an MPEG Movie

Creating and MPEG Movie

1. Select the Application menu icon at the bottom left of the screen, then choose Save Animation > Start Capturing MPEG Movie to display the Record Movie window.
2. Indicate the screen area to be captured:
   - Select Full Screen to capture the entire screen.
   - Select Selected Area to manually select the screen area to capture. Refer to “Selecting an Area for Capture” for more information about selecting the screen area.
3. Select White Background if a white background is desired.
4. Click Start to start recording a movie.

To stop recording an MPEG movie:

1. Click the Animation Recording icon located in the bottom right corner of the screen.

or

Select the Application menu icon and choose Stop Capturing Animation.

2. A dialog box will appear in the center of the screen. Enter a description for the movie in Description field.
3. Click [Create Movie] to create the movie or [Cancel] to cancel the operation.

Creating a JPEG Image Sequence

To start recording a JPEG image sequence:

1. Select the Application menu icon then choose Save Animation > Start Capturing JPEG Images to display the Capture Images window.
2. Indicate the screen area to be captured:
   - Select Full Screen to capture the entire screen.
   - Select Selected Area to manually select the screen area to capture. Refer to “Selecting an Area for Capture” for more information about selecting the screen area.
3. Select White Background if a white background is desired.
4. Click Start to start recording a movie.

To stop recording a JPEG movie:

1. Click the Animation Recording icon located in the bottom right corner of the screen.

or

Select the Application menu icon and choose Stop Capturing Animation.

2. Enter a description for the movie in Description field.
3. Click [OK] to save the images or [Discard Images] to discard the captured images.

Data Export

NOTE: Offline Review Mode only.
NOTE: This option exports data only to the DWS hard drive.

To begin Data Export, select Application menu icon and choose Export to bring up the Data Export window.

Waveform Data

Near the top of the window is a list of the types of data that can be exported. Any or all of them can be selected using the check boxes, and each will be written to its own file. When the user selects any type of data that changes over time (e.g. Waveforms, or Electrode Locations), the Export Interval options become available to choose the time interval for the export.

The Displayed Waveforms option is a special shortcut selection that exports only those waveforms (of any type) that are currently displayed, over the current span of the waveform window. The Export Data and Export Interval options do not apply to this selection.

In EnSite NavX™ mode, if Use System Reference at the top of the window is checked, the Positional Reference will be set to System Reference before the export begins, regardless of its setting during the study. This can standardize the positions of electrodes and labels, but also export them in positions different than how they appear on the screen. If this option is checked, the user must revert the Positional Reference manually after the export is complete.

3. Select the appropriate detection algorithm.
4. Repeat for the roving signal.
5. If using a secondary reference signal, repeat steps 1 and 3.

   NOTE:

   - The user can drag the green Reference Offset line to the desired position, and the system calculates the timing automatically from that position. The aqua-colored line is the reference line placed by the detection algorithm and cannot be moved.
   - Do not change the reference offset after saving the first beat when using Score Map. Changing of the reference offset after the first beat may lead to an incorrect mapping display.
   - Cardiac triggered CFE maps use the same detection algorithm as LAT, P-P, and P-Neg. Non-cardiac CFE maps use the one second screen refresh signal as a trigger. The detection algorithm is not selectable.
   - Detection on the roving waveform takes place within the Roving Activation Interval.

Additional Signals (see Mapping Settings Panel for more information)

Additional ECG or intracardiac signals can be selected to facilitate confirmation of rhythm stability. These signals are only for visualization and are not involved in detection.

Mapping Considerations

CFE Maps

- Multiple detections are possible in a single sample.
- Tick marks in CFE maps are not individually adjustable.
- In CFE maps, some detection settings can be adjusted retrospectively and affect all points in the current map, including Sensitivity, Width, Refractory, the RAI, and Segment Length.
- The Width slider controls the minimum complex width to consider for activation.
- The Refractory slider controls the minimum amount of time between detections.
- The Segment Length slider controls the number of seconds per sample. This control is only available for non-cardiac triggered maps.

Reentrant Maps

- Reentrant maps present the mapping of reentrant arrhythmias and are displayed in a manner similar to LAT maps. The color displayed within the map is linked to the cardiac cycle length (CL) and allows the adjacent display of "early" (white) and "late" (purple) activation times.
- The CL of a Reentrant LAT map is determined by the spacing between the curtains. Adjustment of the CL can be made by clicking and dragging the edge of the curtains to the desired location. The CL will not take effect until the Reentrant checkbox is turned on.

  NOTE: Adjusting the CL and then collecting points may invalidate the map.

Propagation Maps

- Propagation maps display areas of activations times that fall within a specific time interval. The interval can be moved forward through one heart cycle either automatically or by user control.
- Propagation maps can be played in Realtime or RealReview but recordings can only be exported in Offline Review.
- A button beneath the Propagation dropdown controls automatic motion of the activation interval with [Play] and [Freeze] options. [Play] loops over the user-selected cycle length.
- There are two type of Propagation maps available. A mono-color propagation map and a full-color propagation map.
- The speed that the Propagation Maps are played is controlled by the drop-down next to the Play/Sparkle Map button. The speed is related to the amount of time it takes to play through one RAI cycle.

Propagation

- When Propagation is selected, the colors of the map change to purple and white only. The leading edge of the white stripe is brighter than the trailing edge of the stripe to indicate the direction of travel activation.
- Using the side color bar, the stripe can be widened (increasing the interval in milliseconds [ms]), by clicking and dragging above the white stripe. This action can also be accomplished by clicking to the right of the stripe in the color bar at the top of the screen.

Full-Color Propagation

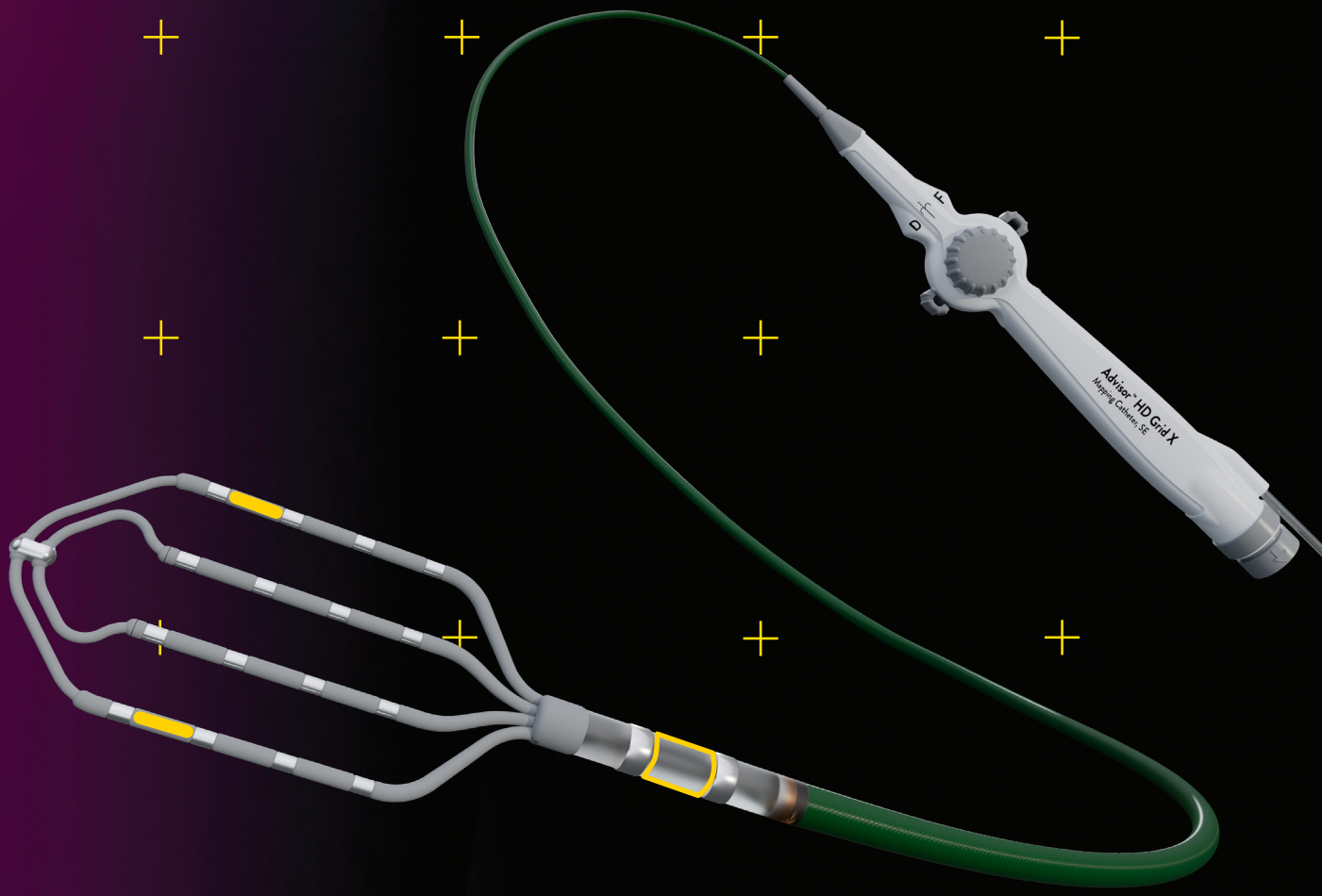
- When Full-Color Propagation is selected, all the colors of the map are used to show the cardiac activation wavefront. The color of the spectrum move through the heart cycle and the map is updated accordingly.

SparkleMap

- The SparkleMap feature allows you to view the activation sequence on top of another map (ex. Voltage map) which allows the physician to simultaneously view multiple datasets on the same anatomic model. The SparkleMap shows the propagation sequence via a series of circular flashes.
- Select the SparkleMap button in the Mapping Tab of the Collect Work Panel to activate.

Abbott

BUILDING ON OUR LEGACY OF ENHANCED MAPPING SPEED AND ACCURACY[1]



INTRODUCING: ADVISOR™ HD GRID X MAPPING CATHETER, SENSOR ENABLED™

Experience the power of next-generation technology with the Advisor HD Grid X Mapping Catheter, SE. This advanced tool is now better than ever, offering a boost in **accuracy, speed,** and **versatility**[1].

We've made advancements to our novel first-generation Advisor™ HD Grid Mapping Catheter, Sensor Enabled™ - which offered a first-of-its-kind electrode configuration for high-density mapping, allowing you to place 16 electrodes where you need them. Our unique first-generation design platform, Advisor HD Grid Mapping Catheter, SE was designed to maneuver bi-directionally within all chambers of the heart.

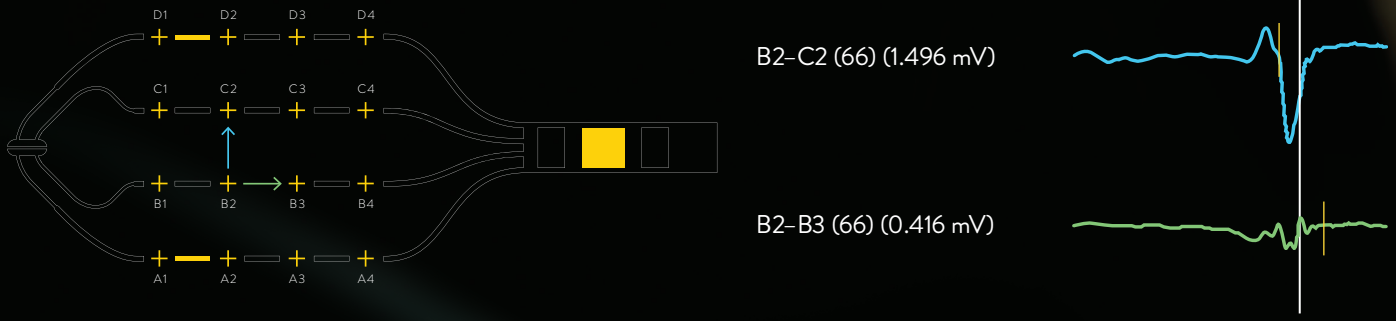
BUILDING ON OUR LEGACY

Leveraging our legacy with the Advisor™ HD Grid Mapping Catheter, Sensor Enabled™, we returned to our roots, building on our foundation and drawing strength from our past. The Advisor HD Grid Mapping Catheter, SE **reduces radiation**[2]**, redo AF procedures**[3]**,** and **identifies gaps often missed** by other circular mapping catheters[4].

	ADVISOR™ HD GRID MAPPING CATHETER, SENSOR ENABLED™	CIRCULAR MAPPING CATHETERS	
AFIB FLUORO TIME[2]	4.1 MIN	15 MIN	
REDO AF PROCEDURES[3]	6%	20%	
GAPS IDENTIFIED FOLLOWING PVI[4]	81.8%	CMC10 36.7%	CMC20 38.9%

PART OF YOUR ONE SYSTEM SOLUTION

The innovative Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™ leverages the advanced capabilities of the EnSite™ X EP System, compatible with EnSite™ VoXel Mode through its **2 additional sensors.** When paired with the EnSite X EP System, the catheter's grid-pattern displays **true*, localized signals** often missed by traditional mapping catheters.



The addition of two paddle sensors to the new Advisor HD Grid X **collect data faster[1], create more accurate unedited models[1],** and enable you to **map with high confidence[1]** in any cardiac chamber**.

*EnSite Omnipolar Technology captures true signals independent of catheter orientation relative to the wavefront.
**Supported by data from a pre-clinical animal study involving 6 subjects. Results are not necessarily indicative of clinical performance.
A preclinical study with the objective of comparing Advisor HD Grid X Mapping Catheter, SE to Octaray and Advisor HD Grid Mapping Catheter, SE. Four participating independent physicians performed the study protocol with each of the HD Grid X Mapping Catheter, SE, Octaray, and Advisor HD Grid Mapping Catheter, SE catheters within the atria and ventricles of each of six swine study subjects. The protocol measured each catheter on (1) mapping and modeling speed; (2) model accuracy; and (3) ectopic burden.

ADVISOR™ HD GRID X MAPPING CATHETER, SENSOR ENABLED™ IS DESIGNED TO LEAD IN SPEED AND ACCURACY*[1]

In a pre-clinical, head-to-head comparison, Advisor HD Grid X Mapping Catheter, SE beats Octaray‡[1] in 3 key areas:

30%

MORE ACCURATE UNEDITED MODELS
than Octaray‡[1]

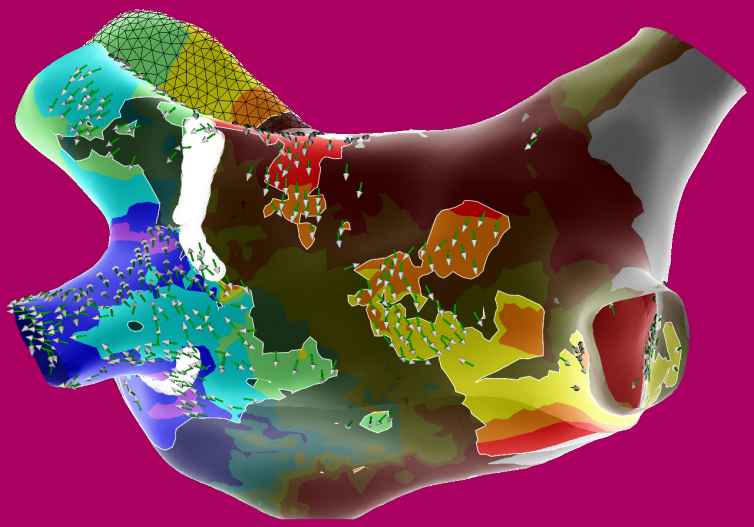
48%

FASTER MAPPING
than Octaray‡[1]

54%

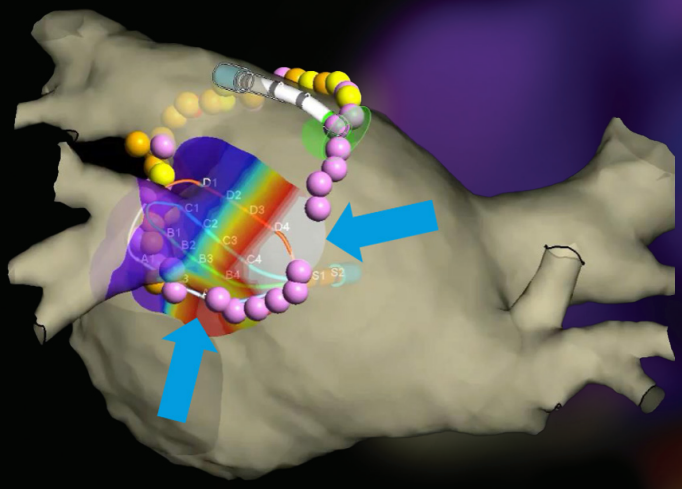
LESS ECTOPY
than Octaray‡[1]

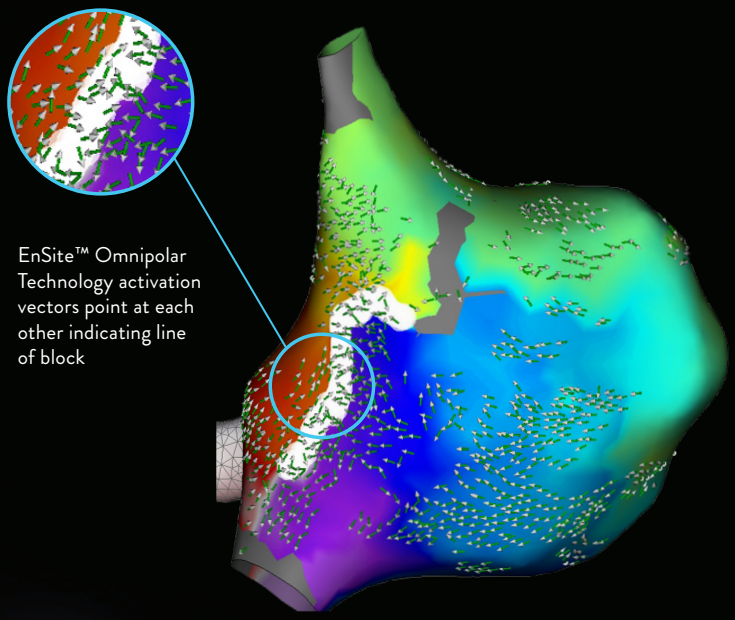
Reduce procedure time[1] with Advisor HD Grid X Mapping Catheter, SE's **expedited data collection and enhanced unedited map quality**[1].



*Supported by data from a pre-clinical animal study involving 6 subjects. Results are not necessarily indicative of clinical performance.
A preclinical study with the objective of comparing Advisor HD Grid X Mapping Catheter, SE to Octaray and Advisor HD Grid Mapping Catheter, SE. Four participating independent physicians performed the study protocol with each of the HD Grid X Mapping Catheter, SE, Octaray, and Advisor HD Grid Mapping Catheter, SE catheters within the atria and ventricles of each of six swine study subjects. The protocol measured each catheter on (1) mapping and modeling speed; (2) model accuracy; and (3) ectopic burden.

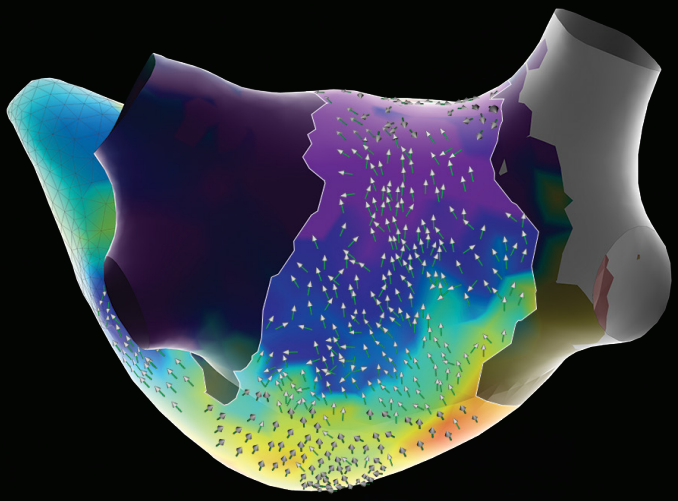
EnSite™ LiveView Dynamic Display **overcomes bipolar blindness**[5] with every beat by displaying mapping data in real-time, beat-by-beat, from the Advisor HD Grid X Mapping Catheter, SE's precise location.





EnSite™ Omnipolar Technology activation vectors point at each other indicating line of block

See every signal in 360 degrees with EnSite™ Omnipolar Technology, capturing signals that no other mapping technology can see**.



Simply, objectively and automatically assess near field signals by isolating **true*, localized signals** with the automated point annotation of EnSite™ OT Near Field software.

Dive into the forefront of cutting-edge mapping technology where unmatched speed, pinpoint accuracy, and unwavering confidence meet.

Get Advisor HD Grid X Mapping Catheter, SE in your lab today.

*EnSite Omnipolar Technology captures true signals independent of catheter orientation relative to the wavefront.

*Supported by data from a pre-clinical animal study involving 6 subjects. Results are not necessarily indicative of clinical performance.
**Every signal can be defined as any signal seen on the RAI window recorded by the Advisor HD Grid Mapping Catheter, SE when the map polarity is set to omnipolar.

1. Abbott. Report on file. 91060435. A preclinical study with the objective of comparing Advisor HD Grid X Mapping Catheter, SE to Octaray and Advisor HD Grid Mapping Catheter, SE. Four participating independent physicians performed the study protocol with each of the HD Grid X Mapping Catheter, SE, Octaray, and Advisor HD Grid Mapping Catheter, SE catheters within the atria and ventricles of each of six swine study subjects. The protocol measured each catheter on (1) mapping and modeling speed; (2) model accuracy; and (3) ectopic burden.
2. Olson N, Lo M, Zahwe F, Gururaj A, Martel JA, Bernard ML, Tao C and Venkataraman R. The effect of dynamic mapping data on procedure efficiency in radiofrequency ablation of patients with atrial fibrillation. Abstracts from the 26th Annual International Atrial Fibrillation Symposium. Journal of Cardiovascular Electrophysiology. 2021;32:1467-1515.
3. Day, J. D., Crandall, B., Cutler, M., Osborn, J., Miller, J., Mallender, C., & Lakkireddy, D. (2020). High Power Ultra Short Duration Ablation with HD Grid Improves Freedom from Atrial Fibrillation and Redo Procedures Compared to Circular Mapping Catheter. Journal of Atrial Fibrillation, 13(2).
4. Porterfield C, et al. Comparison of Gap Identification Using Three Technologies for Confirmation of Pulmonary Vein Isolation. Abbott. Data on File: MAT-2002108 v1.0
5. Deno DC, Bhaskaran A, Morgan DJ, Goksu F, Batman K, Olson GK, Magtibay K, Nayyar S, Porta-Sánchez A, Laflamme MA, Massé S, Aukhojee P, Nair K, Nanthakumar K, High Resolution, Live, Directional Mapping, Heart Rhythm (2020), doi: https://doi.org/10.1016/ j.hrthm.2020.04.039.

Abbott
The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgium, Tel: +32 2 774 68 11
Cardiovascular.abbott

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

MAT-2414206 v1.0 | Item approved for EMEA use.

Abbott

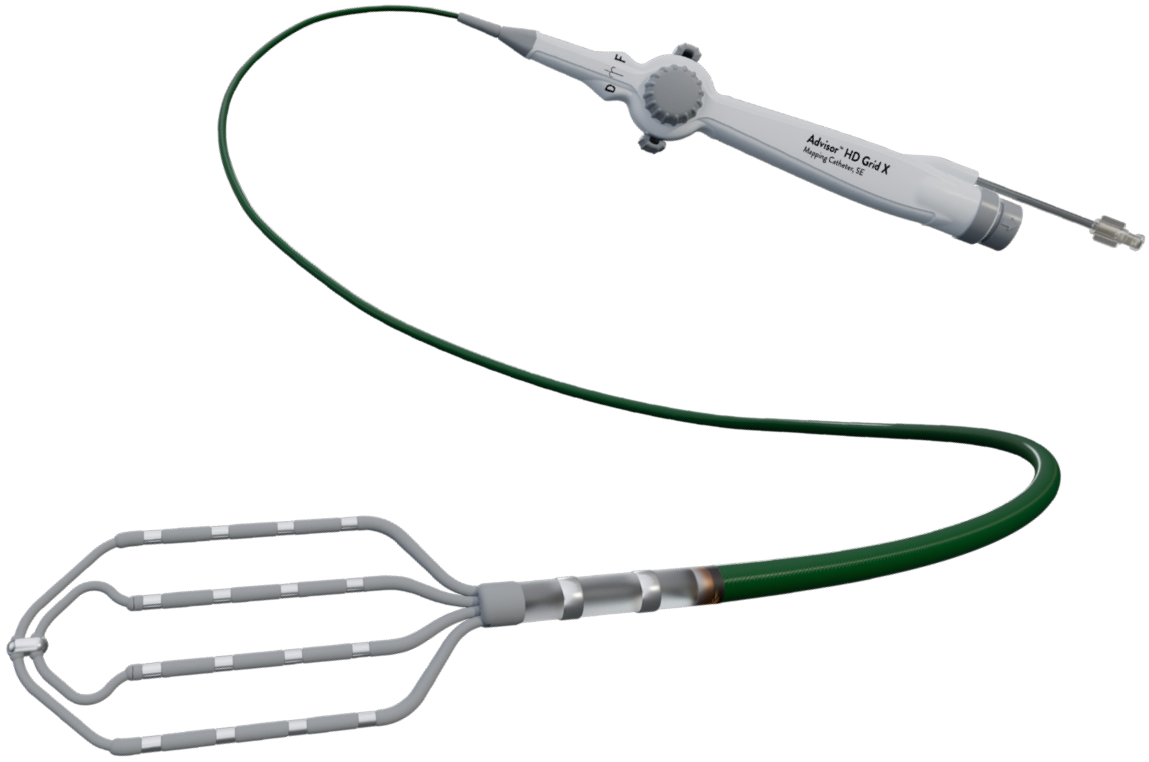
Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™

Description

The latest high-density mapping catheter incorporates additional Sensor Enabled™ coverage throughout the entire electrode array.

Product Highlights

- High-density mapping catheter for atrial and ventricular mapping
- Equidistant spacing along and across the spline
- 1 mm electrodes
- Includes 2 additional magnetic sensors in the distal end of the paddle - in addition to the current shaft sensor



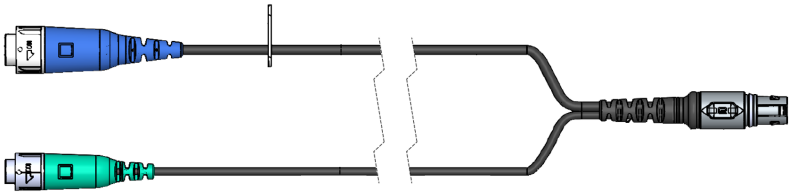
Abbott

Ordering Information

REORDER NUMBER	DESCRIPTION	CURVE	ELECTRODE AND SE PLACEMENT	GRID ELECTRODE SPACING	GRID DIMENSIONS	USABLE LENGTH (CM)
D-AVHDX-DF16	Sensor Enabled™ Bi-D High-Density Mapping Catheter	DF	Grid: 16 x Electrodes 2 x Sensors Shaft: 2 x Electrodes 2 x Sensor	3 mm equidistant spacing	13 x 12mm^2	110

Required Catheter Connecting Cable

REORDER NUMBER	DESCRIPTION	LENGTH (M)
D-ENS-AVHDX-CBL	Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™ 32 pin EnSite™ X connector cable	3.6



Abbott
The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgium, Tel: +32 2 774 68 11
Cardiovascular.abbott

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

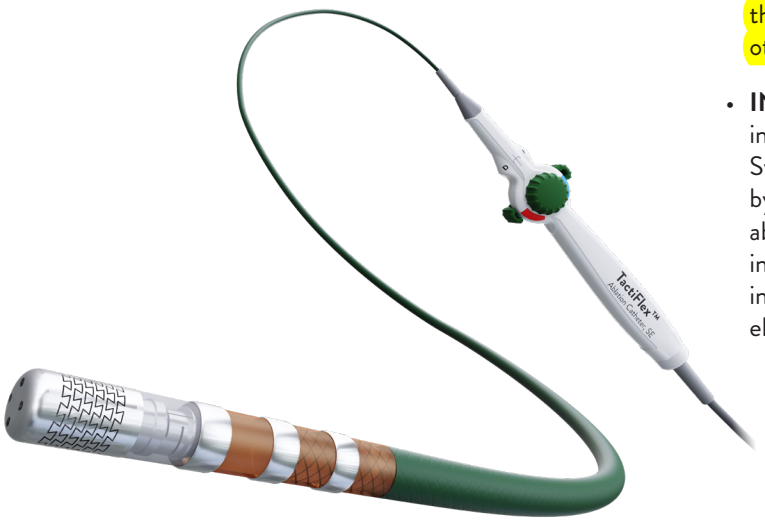
Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™ is a CE marked medical device. CE 2797. Abbott Medical, 5050 Nathan Lane North, Plymouth, Minnesota, 55442 USA

MAT-2414901 v1.0 | Item approved for EMEA use.

TactiFlex™ Ablation Catheter, Sensor Enabled™

Description

Designed for optimal safety and stability, confident lesion creation and procedural efficiency, the TactiFlex™ Ablation Catheter, Sensor Enabled™ elevates ablation procedures through a proprietary tip design and full integration with the revolutionary EnSite™ X EP System.



Product Highlights

- **DESIGNED FOR OPTIMAL SAFETY AND STABILITY** through a flexible laser-cut tip design, experience up to 2X greater stability than conventional 56-hole catheters[1]. Apply directed irrigation flow[2] to the tip-tissue interface, effectively cooling tissue for safe transmural ablation.
- **CONFIDENT LESION CREATION** with the proven performance of the Abbott contact force platform[3]. Optimize contact force measurement through fiber-optic technology that provides high resolution (1g) real-time (50Hz) force display with thermal compensation and no interference from other catheters.
- **INCREASE PROCEDURAL EFFICIENCY**[4] from intuitive handling and usability with full EnSite™ X EP System integration with PVI ablation times reduced by as much as 70%*** with high-power short-duration ablation[5]. Increase usability and predictability with intuitive contact force arrow and deflection direction indicator[6] and monitor lesion creation with excellent electrogram signal quality even during RF.[7]

Ordering Information

TactiFlex™ Ablation Catheter, Sensor Enabled™ must be used with TactiSys™ Quartz, TactiFlex™ Radiofrequency Cable (TSQ-RF-TFSE-CBL) that connects TactiSys™ Quartz Equipment to the Ampere™ RF Generator.

REORDER NUMBER	DESCRIPTION	CURVE	FRENCH SIZE	ELECTRODE SPACING (MM)	TIP ELECTRODE (MM)	LENGTH (CM)
A-TFSE-DD	Bi-D Irrigated Ablation Catheter	D-D	8	2-2-2	4	115
A-TFSE-DF	Bi-D Irrigated Ablation Catheter	D-F	8	2-2-2	4	115
A-TFSE-FF	Bi-D Irrigated Ablation Catheter	F-F	8	2-2-2	4	115
A-TFSE-FJ	Bi-D Irrigated Ablation Catheter	F-J	8	2-2-2	4	115
A-TFSE-JJ	Bi-D Irrigated Ablation Catheter	J-J	8	2-2-2	4	115
A-TFSE-D	Uni-D Irrigated Ablation Catheter	D	8	2-2-2	4	115
A-TFSE-F	Uni-D Irrigated Ablation Catheter	F	8	2-2-2	4	115
A-TFSE-J	Uni-D Irrigated Ablation Catheter	J	8	2-2-2	4	115

1. Ambrosius Nick, Fish Jeffrey, Tranter John, Abbott Laboratories. Flexible, kerfed ablation catheter tip provides superior stability in a bench model [abstract]. In: APHRS 2018: Abstract Book; 2018, October 17-18; Taipei, Taiwan. Abstract nr 1170.
2. Abbott report 90906650.
3. Same contact force technology as in TactiCath Quartz and TactiCath SE, Abbott report 90702721.
4. Nair D et al. Acute Results of a Novel Flexible Tip Radiofrequency Catheter Incorporating Contact Force Sensing. EP Europace. (In press)
5. Ptaszek LM et al. Safe and effective delivery of high-power, short-duration radiofrequency ablation lesions with a novel, flexible-tip radiofrequency ablation catheter [abstract]. In: Heart Rhythm 2021: July 28-31, Boston. Heart Rhythm Volume 18, Issue 9, Supplement. Elsevier; 2021. Abstract nr B-PO02-109.
6. Compared to TactiCath SE and EnSite Precision™. Abbott reports 90486839 and 90773365.
7. Abbott report 90486839.

* Up to 50W
** Compared to TactiCath SE flow rates
*** Compared to standard power ablation (50W vs. 30W)

Abbott
One St. Jude Medical Dr., St. Paul, MN 55117 USA, Tel: 1 651 756 2000
Abbott.com

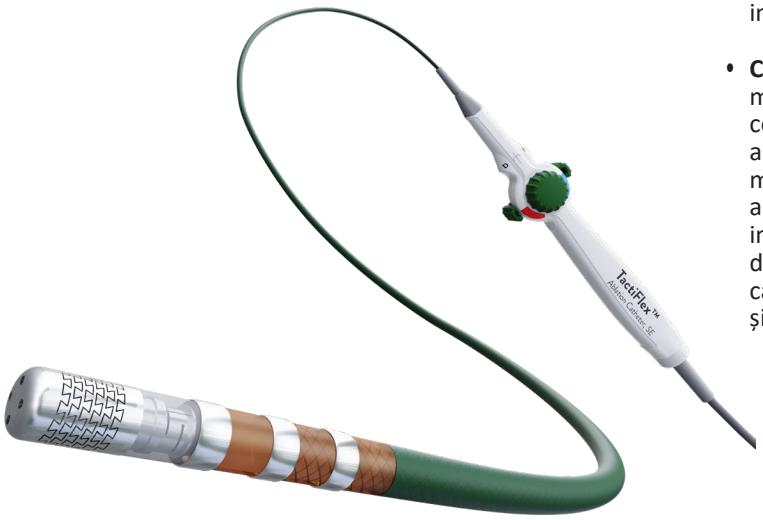
MAT 2109295 v1.0 | Item approved for use outside the United States only.

Abbott

Cateter de ablație TactiFlex™, Sensor Enabled™

Descriere

Conceput pentru siguranță și stabilitate optime, crearea de leziuni cu încredere și eficiență a procedurii, cateterul de ablație TactiFlex™, Sensor Enabled™ îmbunătățește procedurile de ablație printr-un design proprietar al vârfului și o integrare completă cu sistemul revoluționar EnSite™ X EP.



Caracteristici produs

- **CONCEPUT PENTRU SIGURANȚĂ ȘI STABILITATE OPTIME** printr-un design flexibil al vârfului tăiat cu laser, experimentați o stabilitate de până la 2 ori mai mare față de cateterele convenționale cu 56 de orificii[1]. Aplicați un flux de irigare direcționat[2] pe interfața vârf-țesut, răcind eficient țesutul pentru o ablație transmurală sigură.
- **CREAREA DE LEZIUNI CU ÎNCREDERE** cu performanța dovedită a platformei cu forță de contact Abbott[3]. Optimizați măsurarea forței de contact prin tehnologia cu fibră optică ce oferă o afișare a forțelor de înaltă rezoluție (1g) în timp real (50 Hz) cu compensare termică și fără interferențe de la alte catetere.
- **CREȘTEREA EFICIENȚEI PROCEDURALE**[4] prin manipularea intuitivă și aplicabilitate cu integrarea completă a sistemului EnSite™ X EP cu timpi de ablație PVI reduși cu până la 70%*** cu ablația de mare putere de scurtă durată[5]. Sporiți aplicabilitatea și predictibilitatea cu indicatorul intuitiv de direcție a săgeții forței de contact și a deflexiei[6] și monitorizați crearea leziunilor cu o calitate excelentă a semnalului electrogramei chiar și în timpul RF.[7]

Informații de comandă

Cateterul de ablație TactiFlex™, Sensor Enabled™ trebuie utilizat cu TactiSys™ Quartz, cablul de radiofrecvență TactiFlex™ (TSQ-RF-TFSE-CBL) care conectează echipamentul TactiSys™ Quartz la generatorul Ampere™ RF.

NUMĂR DE COMANDĂ	DESCRIERE	CURBĂ	DIM. FRANCEZĂ	DISTANȚARE ELECTROZI (MM)	ELECTROD DE VÂRF (MM)	LUNGIME (CM)
A-TFSE-DD	Cateter de ablație irigat Bi-D	D-D	8	2-2-2	4	115
A-TFSE-DF	Cateter de ablație irigat Bi-D	D-F	8	2-2-2	4	115
A-TFSE-FF	Cateter de ablație irigat Bi-D	F-F	8	2-2-2	4	115
A-TFSE-FJ	Cateter de ablație irigat Bi-D	F-J	8	2-2-2	4	115
A-TFSE-JJ	Cateter de ablație irigat Bi-D	J-J	8	2-2-2	4	115
A-TFSE-D	Cateter de ablație irigat Uni-D	D	8	2-2-2	4	115
A-TFSE-F	Cateter de ablație irigat Uni-D	F	8	2-2-2	4	115
A-TFSE-J	Cateter de ablație irigat Uni-D	J	8	2-2-2	4	115

1. Ambrosius Nick, Fish Jeffrey, Tranter John, Abbott Laboratories. Flexible, kerfed ablation catheter tip provides superior stability in a bench model [abstract]. In: APHRS 2018: Abstract Book; 2018, 17-18 octombrie; Taipei, Taiwan. Abstract nr 1170.
2. Raport Abbott 90906650.
3. Aceeași tehnologie cu forță de contact ca la TactiCath Quartz și TactiCath SE, Raport Abbott 90702721.
4. Nair D și colab. Acute Results of a Novel Flexible Tip Radiofrequency Catheter Incorporating Contact Force Sensing. EP Europace. (In press)
5. Ptaszek LM și colab. Safe and effective delivery of high-power, short-duration radiofrequency ablation lesions with a novel, flexible-tip radiofrequency ablation catheter [abstract]. In: Heart Rhythm 2021: 28-31 iulie, Boston. Heart Rhythm Volume 18, Issue 9, Supplement. Elsevier; 2021. Abstract nr B-PO02-109.
6. Comparativ cu TactiCath SE și EnSite Precision™. Rapoarte Abbott 90486839 și 90773365.
7. Raport Abbott 90486839.

* Până la 50W
** Comparativ cu debitele TactiCath SE
*** Comparativ cu ablația de putere standard (50W față de 30W)

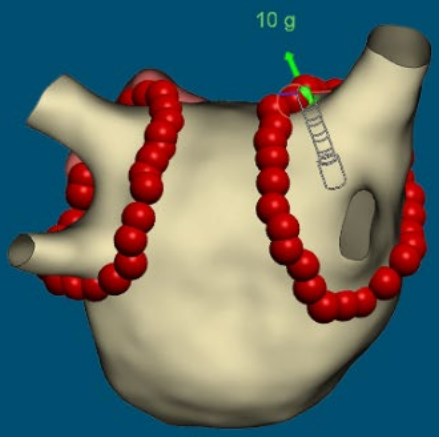
Abbott
One St. Jude Medical Dr., St. Paul, MN 55117 SUA, Tel: 1 651 756 2000 Abbott.com

MAT 2109295 v1.0 | Articol aprobat numai pentru utilizare în afara Statelor Unite.

Perform High-Power Ablation** with Safety and Stability, Confidence and Efficiency

Designed for Optimal Safety and Stability

- Experience superior stability with a unique, flexible, laser-cut tip - up to 2X greater stability than conventional 56-hole catheters[2]
- Apply directed irrigation flow[5] to the tip-tissue interface, effectively cooling tissue for safe transmural ablation
- Lower irrigation rate*** while ablating up to 50W to reduce fluid loading



Confident Lesion Creation

- Ablate with the proven performance of the Abbott contact force platform[6]
- Optimize contact force measurement through fiber-optic technology
- High resolution (1g) real-time (50Hz) force display with thermal compensation and no interference from other catheters

Procedural Efficiency[1] from intuitive handling and usability with full EnSite X EP System integration

- Reduce PVI ablation times by as much as 70%**** with high-power short-duration ablation[7]
- Usability and predictability with intuitive contact force arrow and deflection direction indicator[4]
- Monitor lesion creation with excellent electrogram signal quality even during RF[3]

FlexAbility™ Ablation Catheter, Sensor Enabled™

Product Highlights

- Combines the unique flexible tip with a handle and shaft designed to accurately navigate within the heart
- D, F and J curve options
- Symmetric or asymmetric options
- Ergonomic uni- and bi-directional handles are designed for consistent performance and fatigue reducing enhancements.*
- Integrates with EnSite Precision™ cardiac mapping system and MediGuide™ Technology

Ordering Information

8 F irrigated ablation catheter

Reorder Number	Description	Curve	French Size	Electrode Spacing (mm)	Tip Electrode (mm)	Length (cm)
A-FASE-DD	Sensor Enabled™ Bi-D Irrigated Ablation Catheter	D-D	8	1-4-1	4	115
A-FASE-DF	Sensor Enabled™ Bi-D Irrigated Ablation Catheter	D-F	8	1-4-1	4	115
A-FASE-FF	Sensor Enabled™ Bi-D Irrigated Ablation Catheter	F-F	8	1-4-1	4	115
A-FASE-FJ	Sensor Enabled™ Bi-D Irrigated Ablation Catheter	F-J	8	1-4-1	4	115
A-FASE-JJ	Sensor Enabled™ Bi-D Irrigated Ablation Catheter	J-J	8	1-4-1	4	115
A-FASE-D	Sensor Enabled™ Uni-D Irrigated Ablation Catheter	D	8	1-4-1	4	115
A-FASE-F	Sensor Enabled™ Uni-D Irrigated Ablation Catheter	F	8	1-4-1	4	115
A-FASE-J	Sensor Enabled™ Uni-D Irrigated Ablation Catheter	J	8	1-4-1	4	115

Required Catheter Connecting Cable: Model A-FASE-CBL4

*Compared to ThermoCool™ ablation catheter (BioSense Webster)

The FlexAbility™ Ablation Catheter, Sensor Enabled™, is intended for use with the compatible irrigation pump and a compatible RF cardiac ablation generator. The catheter is intended for creating lesions during cardiac ablation procedures (mapping, stimulation, and ablation) for the treatment of arrhythmias. Sensor Enabled Ablation Catheters are used with compatible magnetic tracking systems to enable catheter positioning and navigation.

Not for sale in the U.S.

SJM-CAG-0915-0035 I Item approved for international use only.

ST. JUDE MEDICAL

Therapy™ Ablation Catheters
4 mm Tip Thermocouple
5 F

Product Highlights

- Uni-directional steering
- Thermocouple temperature measurement
- Push/pull handle

Ordering Information

7 F Quadripolar catheter (1 unit per box)

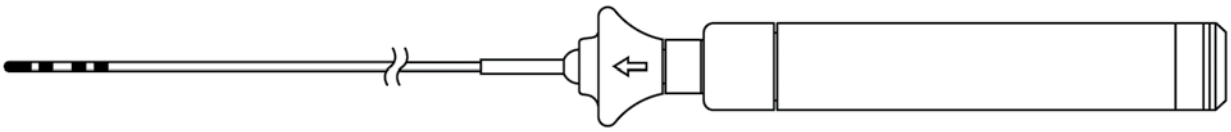
Reorder Number	Description	Electrode Spacing (mm)	Tip Electrode (mm)	Band Electrode (mm)	Curve Type
83351	1304-5-25-M-TE4BE1 (SOFT)	2-5-2	4	1	Medium
83403	1304-5-2-S-TE4BE1	2	4	1	Small

Required Catheter Connecting Cable – Page 164

SJM: 85641

Stockert: 85713, 85709

Medtronic: 85711, 85708



Therapy™ Ablation Catheters
4 & 8 mm Tip Thermocouple
Quadripolar
7 F

Product Highlights

- Uni-directional steering
- Thermocouple temperature measurement
- Push/pull handle

Ordering Information

7 F ablation catheter (1 unit per box)

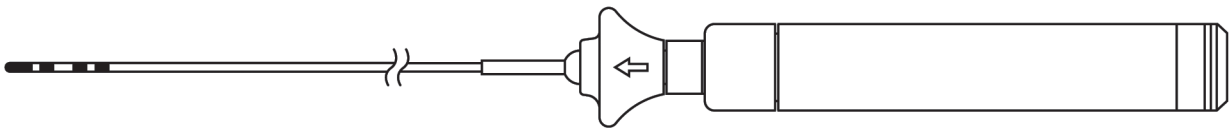
Reorder Number	Description	Electrode Spacing (mm)	Tip Electrode (mm)	Band Electrode (mm)	Curve Type	Usable Length (cm)
83302	1304-7-25-M-TE8	2-5-2	8	2	Medium	110
83306	1304-7-25-L-TE8	2-5-2	8	2	Large	110
83309	1304-7-25-L-TE8A	2-5-2	8	2	Large	110
83311	1304-7-25-XL-TE8A	2-5-2	8	2	X-Large	110
83312	1304-7-25-XL-TE8	2-5-2	8	2	X-Large	110
83404	1304-7-2-M	2	4	2	Medium	110
83405	1304-7-25-M	2-5-2	4	2	Medium	110
83408	1304-7-25-L	2-5-2	4	2	Large	110
83411	1304-7-25-E	2-5-2	4	2	Extended Reach	110
83413	1304-7-2-F	2	4	2	Far Reach	110
83417	1304-7-25-XL	2-5-2	4	2	X-Large	110
83432	1304-7-25-S	2-5-2	4	2	Small	110

Required Catheter Connecting Cable – Page 164

SJM: 85641

Stockert: 85713, 85709

Medtronic: 85711, 85708



Catetere de ablație Therapy™ cu termocuplu și vârf de 4 mm
5 F

Caracteristici produs

- Ghidare unidirecțională
- Măsurarea temperaturii cu termocuplu
- Mâner de împingere/tragere

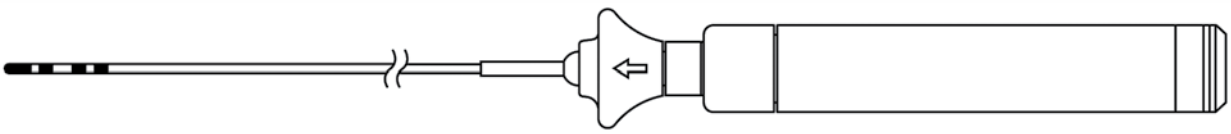
Informații de comandă

Conținut: Cateter de ablație 5 F (1 unitate per cutie)

Număr de re-comandă	Descriere	Spațiere electrozi (mm)	Electrod de vârf (mm)	Electrod bandă (mm)	Tip curbă
83351	1304-5-25-M-TE4BE1 (SOFT)	2-5-2	4	1	Medium
83403	1304-5-2-S-TE4BE1	2	4	1	Small

Cablu de conectare necesar pentru cateter – Pag. 164

SJM: 85641
Stockert: 85713, 85709
Medtronic: 85711, 85708



Catetere de ablație Therapy™ cuadripolare cu termocuplu de vârf de 4 și 8 mm

7 F

Caracteristici produs

- Ghidare unidirecțională
- Măsurarea temperaturii cu termocuplu
- Mâner de împingere/tragere

Informații de comandă

Conținut: Cateter de ablație 7 F (1 unitate per cutie)

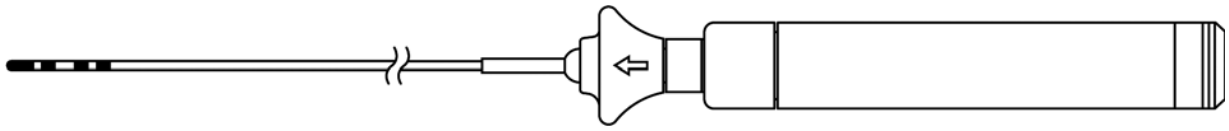
Număr de re-comandă	Descriere	Spațiere electrozi (mm)	Electrod de vârf (mm)	Electrod bandă (mm)	Tip curbă	Lungime utilizabilă (cm)
83302	1304-7-25-M-TE8	2-5-2	8	2	Medie	110
83306	1304-7-25-L-TE8	2-5-2	8	2	Mare	110
83309	1304-7-25-L-TE8A	2-5-2	8	2	Mare	110
83311	1304-7-25-XL-TE8A	2-5-2	8	2	Extra mare	110
83312	1304-7-25-XL-TE8	2-5-2	8	2	Extra mare	110
83404	1304-7-2-M	2	4	2	Medie	110
83405	1304-7-25-M	2-5-2	4	2	Medie	110
83408	1304-7-25-L	2-5-2	4	2	Mare	110
83411	1304-7-25-E	2-5-2	4	2	Acces extins	110
83413	1304-7-2-F	2	4	2	Acces îndepărtat	110
83417	1304-7-25-XL	2-5-2	4	2	Extra mare	110
83432	1304-7-25-S	2-5-2	4	2	Mică	110

Cablu de conectare necesar pentru cateter – Pag. 165

SJM: 85641

Stockert: 85713, 85709

Medtronic: 85711, 85708



Informațiile conținute aici sunt numai pentru distribuția în afara S.U.A.

Catalog internațional de electrofiziologie

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

ENSITE™ X EP SYSTEM

SKIN PREPARATION

Good skin preparation is essential to all electrophysiology studies. Adhering to the steps below helps minimize the noise related to surface electrode and patch placement during EnSite™ X EP System procedures.

1. **TRIM EXCESS HAIR** from all locations where surface electrodes and patches will be used.

2. Prepare the skin surface where ECG and surface electrodes will be placed using the following technique:

   - Gently **ABRADE THE SKIN** using a gauze pad or like material, or using a gel prep (such as Omni Prep) that contains small particles of gritty material. Make sure that all the gel material is removed from the skin.

   - **CLEAN THE SURFACE** with soap and water after the skin has been abraded. Note: Avoid cleaning with isopropyl alcohol unless the skin is excessively oily or covered with lotion.

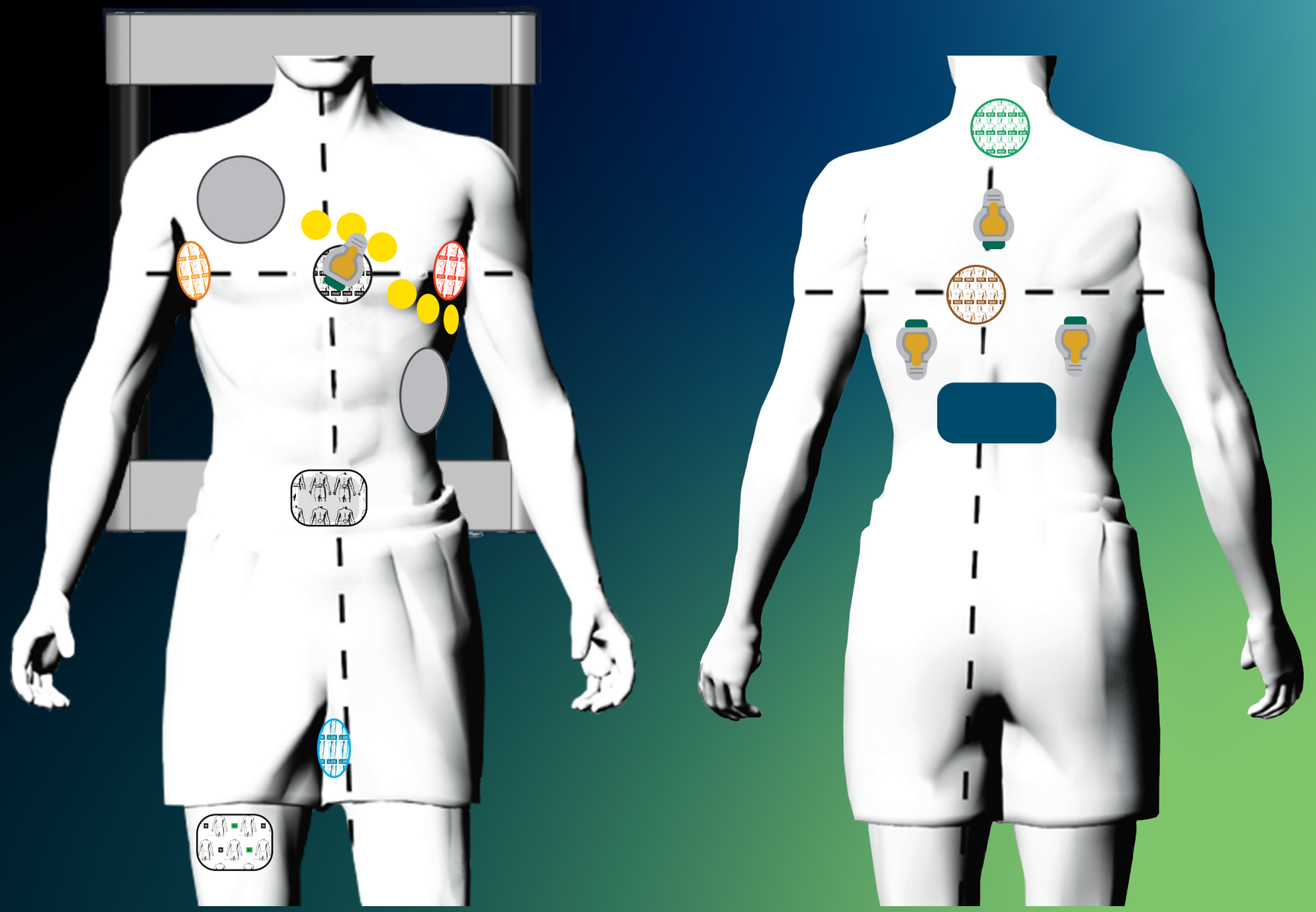
   - Ensure that the **SKIN IS COMPLETELY DRY** and that all alcohol has evaporated before placing any surface electrodes or patches. Note: Press firmly on the center of the surface electrodes with a circular motion to ensure proper contact.

PATIENT PREP DIAGRAM

When placing the EnSite™ X EP System Surface Electrodes on the patient it is important to place them in the correct position, not only in relationship to each other, but also in relationship to other surface electrodes placed for other purposes.

- SYSTEM REFERENCE ELECTRODE
- DEFIBRILLATOR PATCH
- RF DISPERSIVE ELECTRODE
- ENSITE X EP SYSTEM SURFACE ELECTRODES
- RIGHT LEG ECG ELECTRODE
- PATIENT REFERENCE SENSOR PATCH

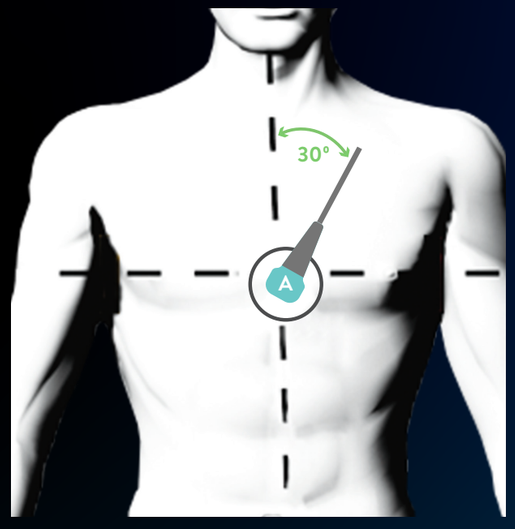
CAUTION: The system reference surface electrode must be the first patient electrode connected to the EnSite™ X EP System Amplifier at the beginning of a study, and the last patient electrode to be disconnected at the end of the study.



PATIENT REFERENCE SENSOR (PRS) PLACEMENT

ANTERIOR PRS (PRS-A)

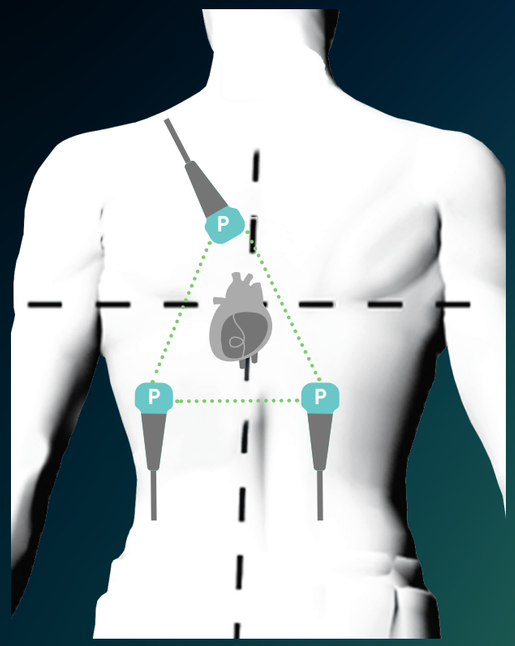
- Orient the patch so the opening for the PRS cable is **30 DEGREES** from the midline and allows the PRS-A cable to be routed over the patent's left clavicle.
- PRS-A must not be inclined more than **45 DEGREES** relative to the patient table.
- PRS patch may be placed on top of the front EnSite™ X EP System Surface Electrode as necessary.
- PRS-A **GREEN SIDE** must be up.



POSTERIOR PRS (PRS-P)

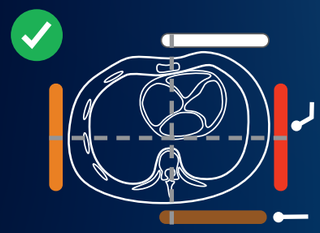
- The patient's heart must fall within the boundaries of the triangle formed by the three back PRS patches.
- The PRS-P sensors must be placed at least **8 CM** from one another.

NOTE: The PRS-P sensors are identical and therefore can be placed in any of the three PRS patches.



SURFACE ELECTRODE ALIGNMENT

Each surface electrode should be placed at a height so that the middle of these surface electrodes is at the same height as the middle of the anterior and posterior surface electrodes.



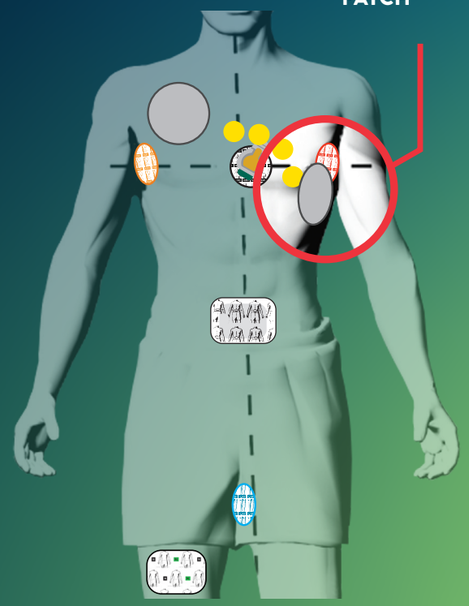
PLACE THE RIGHT AND LEFT SURFACE ELECTRODES SO THEY ARE MIDLINE ON THE SIDES OF THE PATIENT.

PLACE THE POSTERIOR SURFACE ELECTRODE ON THE BACK, DIRECTLY BEHIND THE ANTERIOR SURFACE ELECTRODE.

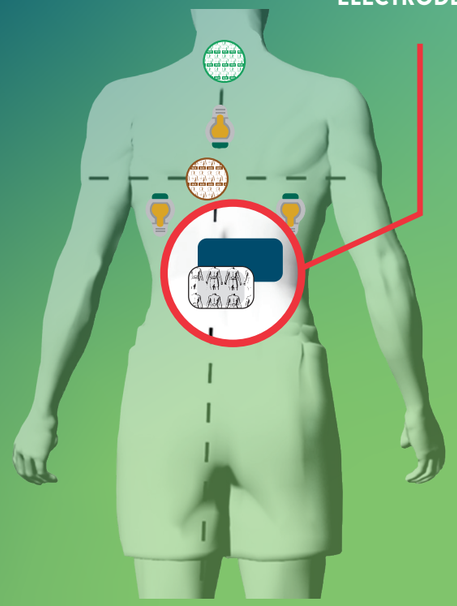
AVOID OVERLAP

None of the surface electrodes should overlap each other or overlap any other surface electrodes used for other purposes. Edge-to-edge contact with ECG electrodes should not create interference. Avoid direct contact of any surface electrode with an RF dispersive electrode. Placement of the EnSite™ X EP System System Reference Electrode should be selected with consideration to the placement of the RF dispersive electrodes. If the electrodes are too close to each other or touching, the ablation catheter can appear to move or shift on the EnSite™ X EP System display when RF energy is being applied.

AVOID OVERLAP WITH DEFIBRILLATOR PATCH



AVOID OVERLAP WITH RF DISPERSIVE ELECTRODE



CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at manuals.sjm.com or eifu.abbottvascular.com for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Abbott
One St. Jude Medical Dr., St. Paul, MN 55117 USA, Tel: 1 651 756 2000
Abbott.com

MAT-2006168 v3.0 | Item approved for use Outside of the United States only.

Abbott

Subsemnatul **CARAMUZI CRISTINA** interpret şi traducător autorizat pentru limba străină germana si engleza în temeiul autorizaţiei nr. 718 din data de 15.10.1998 , eliberată de Ministerul Justiţiei din România, certific exactitatea traducerii efectuate din limba engleza în limba romana, că textul prezentat a fost tradus in totalitate/extras, fără omisiuni, şi că, prin traducere, înscrisului nu i-a fost denaturat conţinutul şi sensul.

INTERPRET ŞI TRADUCĂTOR AUTORIZAT,

TRADUCATOR AUTORIZAT AL MINISTERULUI DE JUSTITIE
CARAMUZI CRISTINA
nr. 718
germană, engleză

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

Holds Certificate Number: **MD 701325**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, Development and Manufacture of Cables/Leads (ECG), Introducers and Needles, Hemostasis and Compression Devices, Catheters, Electrophysiology (EP) Catheters, including RF Ablation Catheters and Electrodes, Radio Frequency (RF) Ablation Generators, Electrosurgical Cables, Diagnostic Guidewires, Guidewires, Return Electrodes, and Accessories.

Warehousing, Distribution, labelling and repackaging of Medical Devices in the following fields: Cardiac Rhythm Management, Electrophysiology, Heart Failure, Neuromodulation, Structural Heart and Vascular.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-02-22
Latest Revision Date: 2023-07-24

Effective Date: 2023-08-18
Expiry Date: 2026-08-17

...making excellence a habit.™

UKAS MANAGEMENT SYSTEMS 0003

Certificate No: **MD 701325**

Location	Registered Activities
Abbott Medical 5050 Nathan Lane North Plymouth Minnesota 55442 USA	Design, Development and Manufacture of Cables/Leads (ECG), Introducers and Needles, Hemostasis and Compression Devices, Catheters, Electrophysiology (EP) Catheters, including RF Ablation Catheters and Electrodes, Radio Frequency (RF) Ablation Generators, Electrosurgical Cables, Diagnostic Guidewires, Guidewires, Return Electrodes, and Accessories.
St. Jude Medical 2305 Walnut Street Roseville Minnesota 55113 USA	Warehousing, Distribution, labelling and repackaging of Medical Devices in the following fields: Cardiac Rhythm Management, Electrophysiology, Heart Failure, Neuromodulation, Structural Heart and Vascular.

Original Registration Date: 2019-02-22

Latest Revision Date: 2023-07-24

Effective Date: 2023-08-18

Expiry Date: 2026-08-17

bsi.

După Royal Charter

Certificat de înregistrare

SISTEM DE MANAGEMENT AL CALITĂȚII - ISO 13485:2016& EN ISO 13485:2016

Aceasta este pentru a certifica faptul că: Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
SUA

Deține Certificatul cu Numărul: **MD 701325**

și operează un sistem de management al calității care respectă cerințele ISO 13485:2016 și EN ISO 13485:2016 pentru următorul domeniu:

Proiectare, dezvoltare și fabricare de cabluri/conducte (ECG), introducetoare și ace, dispozitive de hemostază și compresie, catetere, catetere de electrofiziologie (EP), inclusiv catetere și electrozi de ablație RF, generatoare de ablație de radiofrecvență (RF), cabluri electrochirurgicale, fire de ghidare de diagnosticare, fire de ghidare și accesorii, electrozi de retur.

Depozitarea, Distribuția, etichetarea și reambalarea Dispozitivelor Medicale în următoarele domenii: Managementul Ritmului Cardiac, Electrofiziologie, Insuficiență cardiacă, Neuromodulație, Inimă structurală și Vasculară.

Pentru și în numele BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Data inregistrarii originale: 22-02-2019
Data ultimei revizuiri: 24-07-2023

Data intrării în vigoare: 2023-08-18
Data expirării: 2026-08-17

...făcând excelenţa un obicei"

Certificat Numărul: **MD 701325**

Locație	Activități înregistrate
Abbott Medical 5050 Nathan Lane North Plymouth Minnesota **55442** **STATELE UNITE ALE AMERICII**	Proiectare, Dezvoltare și Fabricare Cabluri/Leads(ECG), introducetori și ace, dispozitive de hemostază și compresie, catetere, catetere de electrofiziologie (EP), inclusiv catetere și electrozi de ablație RF, generatoare de ablație de radiofrecvență (RF), cabluri electrochirurgicale, fire de ghidare de diagnosticare, fire de ghidare, electrozi de retur și accesorii.
St. Jude Medical 2305 Walnut Street Roseville Minnesota **55113** **STATELE UNITE ALE AMERICII**	Depozitarea, distribuția, etichetarea și reambalarea Dispozitivelor Medicale în următoarele domenii: Managementul Ritmului cardiac, electrofiziologie, insuficiență cardiacă, neuromodulație, inimă structurală și vasculară.

Data înregistrării originale: 22-02-2019
Data ultimei revizuiri: 24-07-2023

Data intrării în vigoare: 2023-08-18
Data expirării: 2026-08-17

Subsemnatul **DUMITRACHE CRISTINA** interpret şi traducător autorizat pentru limba străină engleza în temeiul autorizaţiei nr. 4044 din data de 11.12.2000 , eliberată de Ministerul Justiţiei din România, certific exactitatea traducerii efectuate din limba engleza în limba romana, că textul prezentat a fost tradus in totalitate, fără omisiuni, şi că, prin traducere, înscrisului nu i-a fost denaturat conţinutul şi sensul.

INTERPRET ŞI TRADUCĂTOR AUTORIZAT,

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Abbott Medical
One St. Jude Medical Drive
St. Paul
Minnesota
55117-9913
USA

Holds Certificate Number: MD 728710

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design and development, manufacture, servicing and distribution of ablation generators, radiofrequency generators, ultrasound imaging systems, cardiac mapping and recording systems, cardiac stimulation system, contact force monitoring systems, and signal transmission, including associated hardware, software, and non-sterile accessories. The servicing of cardiac positioning and navigation systems.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2021-03-05
Effective Date: 2024-02-07
Latest Revision Date: 2025-01-06
Expiry Date: 2027-02-06

...making excellence a habit.™